FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: A-200SL-OR3-C

Product name(s): LEPTOSAR 200 SL

Chemical active substance:

acetamipryd, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization

Applicant: CIECH Sarzyna S.A.

Submission date: 23/02/2021

Correction on: 25/10/2021

Correction on: 23/11/2021

Correction on: 22/12/2021

MS Finalisation date: 01/07/2022

Version history

When	What
February 2021	First submission for product authorization in Poland
May 2021	Submission to the evaluation unit Merit Mark
October 2021	Correction of first submission for product authorization in Poland.
November 2021	Correction of first submission for product authorization in Poland.
December 2021	Correction of first submission for product authorization in Poland.
December 2021	zRMS finalised dRR evaluation
July 2022	Final version prepared by zRMS after Commenting period

Table of Contents

9 Ecotoxicology (KCP 10)

Review Comments:

This document describes the acceptable use conditions required for authorization of A-200SL-OR3-C / LEPTOSAR 200 SL a Soluble concentrate (SL) containing 200 g/L Acetamiprid for use as an insecticide.

This Part B document only reviews data and additional information that has not previously been considered within the EU review process.

Since this document is based on the information provided by the Applicant, all review comments, additions and corrections have been made using commenting boxes or highlighted in grey. Any incorrect data or text not evaluated by the zRMS has been crossed out.

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

Field of use: insecticide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1.	PL	Winter oilseed rape (BRSNW)	F	Pollen Beetles (Meligethes aeneus) – MELIAE	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-69	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
2.	PL	Winter oilseed rape (BRSNW)	F	Rape stem weevil (*Ceutorhynchus napi*) - CEUTNA	Foliar spray	After reaching thresholds or after warning service appeal ~~BBCH 17-59~~ BBCH 30-59	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
3.	PL	Winter oilseed rape (BRSNW)	F	Cabbage stem weevils (*Ceutorhynchus pallidactylus*) – CEUTQU	Foliar spray	After reaching thresholds or after warning service appeal ~~BBCH 17-59~~ BBCH 30-59	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
4.	PL	Winter oilseed rape (BRSNW)	F	Cabbage seed weevil (*Ceutorhynchus obstrictus*) – CEUTAS	Foliar spray	After reaching thresholds or after warning service appeal	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-

						BBCH 59-71							
5.	PL	Winter oilseed rape (BRSNW)	F	Brassica pod midge (*Dasineura brassicae*,) - DASYBR	Foliar spray	After reaching thresholds or after warning service appeal BBCH 59-71	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
6.	PL	Maize (ZEMAX)	F	European corn borer (*Ostrinia nubilalis*) - PYRUNU	Foliar spray	After reaching thresholds or after warning service appeal BBCH 51-75	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	300-500	n.a.	-

Minor uses according to Article 51 (zonal uses)													
41.	PL	Spring oilseed rape (BRSNS) white mustard (SINAL); black mustard (BRSNI), Chinese mustard (BRSJU) turnip rape (BRSRO)	F	Pollen beetles (*Meligethes aeneus*) – MELIAE	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-69	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
42.	PL	Spring oilseed rape (BRSNS) white mustard (SINAL); black mustard (BRSNI), Chinese mustard (BRSJU) turnip rape (BRSRO)	F	Rape stem weevil (*Ceutorhynchus napi*) - CEUTNA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 20-59	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
43.	PL	Spring oilseed rape (BRSNS) white mustard (SINAL); black mustard (BRSNI), Chinese mustard (BRSJU) turnip rape (BRSRO)	F	Cabbage stem weevils (*Ceutorhynchus pallidactylus*) – CEUTQU	Foliar spray	After reaching thresholds or after warning service appeal BBCH 20-59	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
44.	PL	Spring oilseed rape (BRSNS) white mustard (SINAL); black mustard (BRSNI), Chinese mustard (BRSJU) turnip rape (BRSRO)	F	Cabbage seed weevil (*Ceutorhynchus obstrictus*) – CEUTAS	Foliar spray	After reaching thresholds or after warning service appeal BBCH 59-71	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
45.	PL	Spring oilseed rape (BRSNS); white mustard (SINAL); black mustard (BRSNI), Chinese mustard (BRSJU); turnip rape (BRSRO)	F	Brassica pod midge (*Dasineura brassicae*,) - DASYBR	Foliar spray	After reaching thresholds or after warning service appeal BBCH 59-71	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
46.	PL	Flax (LIUUT) - seeds and fiber production	F	Large flax flea beetle (*Aphthona euphorbiae*) - APHTEU; Small flax flea beetle (*Longitarsus parvulus*) - LONIPA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 10-14	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-

47.	PL	Flax (LIUUT) -seeds and fiber production	F	Cabbage thrips (*Thrips angusticeps*) - THRIAN; Flax thrips (*Thrips lini)* - THRILI	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-61	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
48.	PL	Common hemp (CNISA**)** - seeds and fiber production	F	Hemp flea beetle (*Psylliodes attenuata*) - PSYIAT	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-14	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
49.	PL	Common hemp (CNISA**)** - seeds and fiber production	F	European maize borer (*Ostrinia nubilalis*) - PYRUNU	Foliar spray	After reaching thresholds or after warning service appeal (June)	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
50.	PL	Common hemp (CNISA**)** - seeds and fiber production	F	Aphids (*Aphididae*) – APXXSP; Thrips (*Thysanoptera*) - 1THYSO	Foliar spray	After reaching thresholds or after warning service appeal (BBCH 39-59)	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
51.	PL	Soybean (GLXMA) – seeds production	F	Sitona (*Sitona sp.*) - SITNSP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-19	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-500	n.a.	-
52.	PL	Soybean (GLXMA) – seeds production	F	Bishop bug (*Lygus rugulipennis*) – LYGURU; Aphids (*Aphididae*) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 61-65	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-500	n.a.	-
53.	PL	Opium poppy (PAPSO) – seeds production	F	Capsule midge (*Dasineura papaveris*) -DASYPA; Capsule weevils (*Neoglocianus maculaalba*) - CEUTMA	Foliar spray	After reaching thresholds or after warning service appeal	a) 1 b) 1	n.a.	a) 0,15 l/ha b) 0,15 l/ha	a) 30 g/ha b) 30 g/ha	200-400	n.a.	-

						BBCH 10-39							

54.	PL	Sunflower (HELAN) – seeds production	F	Aphids (*Aphididae*) – APXXSP; Lygus bug (*Lygus sp.*) - LYGUSP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 10-65	a) 1 b) 1	n.a.	~~a) 0,3 l/ha~~ ~~b) 0,3 l/ha~~ a) 0,25 l/ha b) 0,25 l/ha	~~a) 60 g/ha~~ ~~b) 60 g/ha~~ a) 50 g/ha b) 50 g/ha	300-500	n.a.	-
55.	PL	Pumpkin (CUUPE) – seeds production	F	Lygus bug (*Lygus sp.*) - LYGUSP	Foliar spray	After reaching thresholds or after warning service appeal ~~BBCH 21-69~~ BBCH ≥50	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-500	n.a.	-
56.	PL	sugar maize Zea mays L. convar. saccharata Koern. (ZEAMS); Popcorn (ZEAME); sorghum (SORVU), proso true millet (PANMI)	F	European corn borer *(Ostrinia nubilalis)* - PYRUNU; Aphids (*Aphididae*) – APXXSP;	Foliar spray	After reaching thresholds or after warning service appeal BBCH 51-75	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	300-500	n.a.	-
57.	PL	Spring rye (SECCS), Durum wheat (TRZDU), Spelt wheat (TRZSP), einkorn wheat (TRZMO) emmer wheat (TRZDI)	F	Cereal leaf beetle (*Oulema melanopus*) – LEMAME	Foliar spray	After reaching thresholds or after warning service appeal BBCH 37-65	a) 1 b) 1	n.a.	a) 0,2 l/ha b) 0,2 l/ha	a) 40 g/ha b) 40 g/ha	200-400	n.a.	-
58.	PL	Spring rye (SECCS), Spring triticale (TTLWS), Durum wheat (TRZDU), Spelt wheat (TRZSP), einkorn wheat (TRZMO) emmer wheat (TRZDI)	F	Cereal bug (*Eurygaster maura*)- EURYMA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-59	a) 1 b) 1	n.a.	a) 0,2 l/ha b) 0,2 l/ha	a) 40 g/ha b) 40 g/ha	200-400	n.a.	-
59.	PL	Spring wheat (TRZAS)	F	Cereal bug (*Eurygaster maura*)- EURYMA	Foliar spray	After reaching thresholds or	a) 1 b) 1	n.a.	a) 0,2 l/ha b) 0,2 l/ha	a) 40 g/ha b) 40 g/ha	200-400	n.a.	-

						after warning service appeal BBCH 30-59							

60.	PL	Winter wheat (TRZAW)	F	Cereal bug (*Eurygaster maura*)- EURYMA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-59	a) 1 b) 1	n.a.	a) 0,2 l/ha b) 0,2 l/ha	a) 40 g/ha b) 40 g/ha	200-400	n.a.	-
61.	PL	Winter triticale (TTLWI), Winter rye (SECCW)	F	Cereal bug (*Eurygaster maura*)- EURYMA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-59	a) 1 b) 1	n.a.	a) 0,2 l/ha b) 0,2 l/ha	a) 40 g/ha b) 40 g/ha	200-400	n.a.	-
62.	PL	tomato (LYPES), aubergine (SOLME), Paprika (CPSAN)	G	Glasshouse whitefly(*Trialeurodes vaporariorum*) – TRIAVACommon cotton thrips (*Thrips tabaci*) – THRITB; Western grass thrips (*Frankliniella occidentalis*) - FRANOC; Leaf miner (*Phytomyza sp.)* - PHYYSP; Aphids (*Aphididae*) – APXXSP; , Lygus bug(*Lygus sp.)* - LYGUSP; Flea beetle (*Psylliodes*) - 1PSYIG	Foliar spray	After reaching thresholds or after warning service appeal BBCH 20 – 89	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	300-750	3	-
63.	PL	Wild apple (MABSY)	F	Aphids (*Aphididae*) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal ~~BBCH 11-87~~ BBCH 51 - 87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
64.	PL	Wild apple (MABSY)	F	Codling moth (*Cydia pomonella*) - CARPPO	Foliar spray	After reaching thresholds or after warning service appeal BBCH 69-74	a) 2 b) 2	7-14	a) 0,125 L/ha b) 0,25L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
65.	PL	Wild apple (MABSY)	F	Pear leaf blister moth (*Leucoptera scitella*) -	Foliar spray	After reaching thresholds or	a) 1	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-

				LEUCSC		after warning service appeal BBCH 57-69	b) 2						
66.	PL	Wild apple (MABSY)	F	Apple fruit sawfly (*Hoplocampa testudinea*) - HOPLTE	Foliar spray	After reaching thresholds or after warning service appeal BBCH 65-69	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
67.	PL	Wild apple (MABSY)	F	Apple leaf midge (*Dasineura mali*) - DASYMA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 59-73	a) 2 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25g/ha b) 50 g/ha	200-750	14	-
68.	PL	Wild apple (MABSY)	F	Bracken clock (*Phyllopertha horticola*) - PHPHHO	Foliar spray	After reaching thresholds or after warning service appeal BBCH 59-73	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
69.	PL	Pear (PYUCO), Chinese pear (PYUPY)	F	Aphids (Aphididae) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal ~~BBCH 11-87~~ BBCH 51 - 87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
70.	PL	Pear (PYUCO), Chinese pear (PYUPY)	F	Codling moth (*Cydia pomonella*) - CARPPO	Foliar spray	After reaching thresholds or after warning service appeal BBCH-71-87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
71.	PL	Pear (PYUCO), Chinese pear (PYUPY)	F	Cherry slug sawfly(*Caliroa limacina*) - ERICLI	Foliar spray	After reaching thresholds or after warning service appeal	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-

						BBCH 71-87							
72.	PL	Pear (PYUCO), Chinese pear (PYUPY)	F	Apple bud weevil(*Anthonomus piri*) - ANTHPY	Foliar spray	After reaching thresholds or after warning service appeal BBCH 51-59	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
73.	PL	Pear (PYUCO), Chinese pear (PYUPY)	F	Pear leaf midge (*Dasineura pyri*) - DASYPY	Foliar spray	After reaching thresholds or after warning service appeal BBCH 71-79	a) 2 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
74.	PL	Pear (PYUCO), Chinese pear (PYUPY)	F	Pear psylla (*Cacopsylla pyri*) - PSYLPI; Pear sucker (*Cacopsylla pyrisuga*) - PSYLPY; , Pear psyllid (*Cacopsylla pyricola*) - PSYLPC	Foliar spray	After reaching thresholds or after warning service appeal ~~BBCH 11-87~~ BBCH 51 - 87	a) 2 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
75.	PL	Quince (CYDOB), medlar (MSPGE)	F	Aphids (*Aphididae*) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal ~~BBCH 11-87~~ BBCH 51 - 87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
76.	PL	Quince (CYDOB), medlar (MSPGE)	F	Codling moth (*Cydia pomonella*) - CARPPO	Foliar spray	After reaching thresholds or after warning service appeal BBCH 71-87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
77.	PL	Sour cherry (PRNCE), sweet cherry (PRNAV),	F	Cherry fruit fly (*Rhagoletis cerasi*) - RHAGCE	Foliar spray	After reaching thresholds or after warning service appeal BBCH 76-81	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-

78.	PL	Sour cherry (PRNCE), sweet cherry (PRNAV),	F	Aphids (*Aphididae*) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal ~~BBCH 11-87~~ BBCH 51 - 87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	250-750	14	-
79.	PL	Sour cherry (PRNCE), sweet cherry (PRNAV),	F	Cherry slug sawfly (*Caliroa limacina*) - ERICLI	Foliar spray	After reaching thresholds or after warning service appeal BBCH 71-87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
80.	PL	Sour cherry (PRNCE), sweet cherry (PRNAV),	F	Cherry fruit moth (*Argyresthia ephippiella*) - ARGYEP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 51-59	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
81.	PL	Sour cherry (PRNCE), sweet cherry (PRNAV),	F	Cherry-stone weevil (*Anthonomus rectirostris*) - ANTHRE	Foliar spray	After reaching thresholds or after warning service appeal BBCH 57-69	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
82.	PL	Sour cherry (PRNCE), sweet cherry (PRNAV),	F	Apple brown tortrix (*Pandemis heparana*) - PANDHE; Reticulated tortrix (*Adoxophyes orana*) - CAPURE; European leaf roller (*Archips rosana*) - CACORO; Whelk (*Tortricidae*) - 1TORTF; and other leaf caterpillars	Foliar spray	After reaching thresholds or after warning service appeal ~~BBCH 11-87~~ BBCH 51 - 87	a) 2 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25g/ha b) 50 g/ha	200-750	14	-
83.	PL	Peach (PRNPS), Nectarine (PRNPN),apricot (PRNAR)	F	Apple brown tortrix (Pandemis heparana) - PANDHE; Reticulated tortrix (Adoxophyes orana) - CAPURE; European leaf roller (Archips rosana) -	Foliar spray	After reaching thresholds or after warning service appeal ~~BBCH 11-87~~ BBCH 51 - 87	a) 2 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a)25 g/ha b) 50 g/ha	200-750	14	-

				CACORO; Whelk (Tortricidae) - 1TORTF; and other leaf caterpillars									
84.	PL	Peach (PRNPS), Nectarine (PRNPN),apricot (PRNAR)	F	Aphids (*Aphididae*) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal ~~BBCH 11-87~~ BBCH 51 - 87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
85.	PL	Plum (PRNDO)	F	Aphids (*Aphididae*) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal ~~BBCH 11-87~~ BBCH 51 - 87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
86.	PL	Plum (PRNDO)	F	Plum fruit sawfly (*Hoplocampa minuta*) - HOPLMI; Plum sawfly (*Hoplocampa flava*) - HOPLFL;	Foliar spray	After reaching thresholds or after warning service appeal BBCH 69-87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
87.	PL	Plum (PRNDO)	F	Plum fruit moth (*Laspeyresia funebrana*) - LASPFU	Foliar spray	After reaching thresholds or after warning service appeal BBCH 71-81	a) 2 b) 2	14-21	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
88.	PL	Plum (PRNDO)	F	European brown scale (*Parthenolecanium corni*) - LECACO	Foliar spray	After reaching thresholds or after warning service appeal BBCH 54-59	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25g/ha b) 50 g/ha	200-750	14	-
89.	PL	Plum (PRNDO)	F	Apple brown tortrix (*Pandemis heparana*) - PANDHE; Reticulated tortrix (*Adoxophyes orana*) - CAPURE; European leaf roller	Foliar spray	After reaching thresholds or after warning service appeal ~~BBCH 11-87~~	a) 2 b) 2	7-10	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-

				(*Archips rosana*) - CACORO; Whelk (*Tortricidae*) - 1TORTF; and other leaf caterpillars		BBCH 51 - 87							
90.	PL	Hazelnut (CYLAV)	F	Aphids (Aphididae) – APXXSP; , Hazelnut weevil (*Curculio nucum*) - CURCNU; *(Oberea linearis)* - OBERLI; European brown scale (*Parthenolecanium corni*) - LECACO; , Reticulated tortrix (*Adoxophyes orana*) - CAPURE; European leaf roller (*Archips rosana*) - CACORO; other totrix and other leaf caterpillars	Foliar spray	After reaching thresholds or after warning service appeal ~~BBCH 11 – 65~~ BBCH 51 - 65	a) 2 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
91.	PL	walnut (IUGRE)	F	Aphids (Aphididae) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 50 – 65	a) 2 b) 2	10-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
92.	PL	Tobacco (NIOTA)	F	Common cotton thrips (*Thrips tabaci*) - THRITB; Aphids (Aphididae) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal ~~BBCH 11 – 85~~ ~~BBCH 30 – 85~~ ~~BBCH 40-85~~	a) 2 b) 2	7-10	a) 0,125 L/ha b) 0,25 L/ha	a) 25g/ha b) 50 g/ha	200-750	na	-
						BBCH 30-39	a) 1 b) 1	-	a) 0.125 L/ha b) 0.125 L/ha	a) 25g/ha B) 25g/ha			
93.	PL	Common osier (SAXVI) Purple willow (SAXPU)	F	Aphids (Aphididae) – APXXSP, Balsam poplar leaf beetle (*Chrysomela populi*) - CHRSPO; (Chrysomela saliceti)- CHRSSA, Blue willow beetle (*Phratora vulgatissima*) - PHRRVU; Brassy willow leaf beetle	Foliar spray	After reaching thresholds or after warning service appeal ~~BBCH 11-69~~ BBCH 51 - 69	a) 2 b) 2	10	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	na	-

				(*Phratora vitellinae*) - PHRRVI; Cream-bordered green pea moth (*Earias clorana*) - EARICH; , Gall midge (*Dasineura marginemtorquens*) - RHABMA									
94.	PL	Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations	F	Aphids (*Aphididae*) – APXXSP, Springtails (*Collembola*) - 1COLLO; Larch case-bearer (*Coleophora laricella*) - COLELA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-69	a) 1 b) 1	n.a.	~~a) 0,25 L/ha~~ ~~b) 0,25 L/ha~~ a) 0,20 L/ha b) 0,20 L/ha	~~a) 50 g/ha~~ ~~b) 50 g/ha~~ a) 40 g/ha b) 40 g/ha	200-400	na	-

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

9.1.1 Overall conclusions

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Birds

The acute screening assessment for birds exposed to LEPTOSAR 200SL revealed that the TER_A values are above the trigger of 10 showing no potential acute risk for birds. According to the results of the refined long-term risk assessment for Acetamiprid, the TER_{LT} are above the trigger of 5 showing no potential long-term risk for birds.
There is no risk expected from the estimation on acute and long-term risk for birds exposed to Acetamiprid through consumption of contaminated water.

Mammals

According to the results of the acute risk assessment for LEPTOSAR 200SL values are above the trigger of 10 showing no potential acute risk for mammals. Acceptable long term risk to mammals was confirmed using the following refinements:

- Focal species
- Deposition factor (DF) based on interception (IF) by crop (oilseed rape) dependent on growth stage
- PD

According to the refined long-term risk assessment for LEPTOSAR 200SL, ~~the TER_{LT} are above the trigger of 5 showing no potential long-term risk for mammals.~~ all TER values exceed the relevant triggers indicating that LEPTOSAR 200 SL does not pose an unacceptable risk to mammals following applications according to recommended and accepted use pattern (for tobacco at BBCH 30-39 only one application is allowed).

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

Performed risk evaluation demonstrated that following risk mitigation measures are deemed necessary to demonstrate acceptable risk to aquatic organisms following application of LEPTOSAR 200SL:

- ~~For application in tomato (also *aubergine and paprika*): no mitigation measure required~~
- ~~For application in maize, pumpkin, winter oilseed rape and other minor uses crops (*Flax, common hemp, soybean, sunflower, opium poppy*) : 30m vegetated filter strip is required~~
- ~~For application in winter cereals: 20 m vegetated filter strip is required~~
- ~~For application in spring cereals and spring oilseed rape: 20 m buffer zone is required~~
- ~~For application in Ornamental and nurseries: 70 m vegetated filter strip is required~~
- ~~For application in orchards (crops i.e.: *wild apple, pear, quince, sour cherry, peach, plum, nut, tobacco, common osier and purple willow*): 50 m vegetated filter strip is required~~
- ~~For application in *opium poppy*: 20 m vegetated filter strip is required~~

- ~~For application in tomato (also *aubergine and paprika*): no mitigation measure required~~
- For application in **maize**: 20m non-sprayed buffer zone and 20m vegetated filter strip with 50 % nozzle reduction is required
- For application in **winter oilseed rape** and other minor uses crops (Flax, common hemp): 20m non-sprayed buffer zone and 20m vegetated filter strip with 50 % nozzle reduction is required.
- For application in **sunflowe**r: 20m non-sprayed buffer zone and 20m vegetated filter strip with 50 % nozzle reduction is required.

- For application in **winter cereals**: 20 m non-sprayed buffer zone and 20m vegetated filter strip is required
- For application **in pumpkin**: 20m non-sprayed buffer zone and 20m vegetated filter strip with 50 % nozzle reduction is required.
- For application in **soybean**: 20 m no-spray buffer zone with 50% nozzle reduction or 30m no-spray buffer zone is required.
- For application in **spring oilseed rape**: 30 m no-spray buffer zone is required.
- For application in **spring cereals**: 20 m no-spray buffer zone is required
- For application in **ornamental** and nurseries: 20 m vegetated buffer strip with 30m non-sprayed buffer zone and 90 % nozzle reduction is required.
- For application in **orchards** (crops i.e.: wild apple, pear, quince, sour cherry, peach, plum, nut, tobacco, common osier and purple willow): 20 m vegetated filter strip with 20m buffer zone and 90% nozzle reduction is required or 20 m vegetated filter strip with 50m non-sprayed buffer zone
- For application in **opium poppy**: 20 m no-spray buffer zone is required.

9.1.1.3 Effects on bees (KCP 10.3.1)

All the calculated values were less than respective triggers, indicating that the active substances pose a low risk to bees. Therefore a low risk to bees is expected from the application of LEPTOSAR 200 SL following application according to the proposed GAP.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

Applicant decided to start the studies on arthropods from extended laboratory studies because predicted unsatisfactory results in Tier I (laboratory studies on glass plate).

Based on results obtained for LEPTOSAR 200 SL in extended laboratory studies (Tier II) on *T. pyri, A. rhopalosiphi, Ch. carnea* and *C. septempunctata* the corresponding "in-field" hazard quotients are above the trigger value of 1 indicating an unacceptable "in-field" risk to non-target arthropods, following application of LEPTOSAR 200 SL according to the proposed GAP.

~~Performed risk assessment for the "off-field" exposure demonstrated that formulation Leptosar 200 SL poses unacceptable risk to off-field population of non-target arthropods after use in crops grouping in "fruit crops scenario" one and two application. For these crops an acceptable risk is indicated when the risk mitigation measure (75% drift reducing nozzles are required when a no-spray buffer zone of 3 m is respected or 50% drift reducing nozzles are required when a no-spray buffer zone of 5 m is respected) is applied.~~

The available data on aged residue studies indicate that, any initial effects on non-target arthropods from the proposed uses of LEPTOSAR 200 SL will be short-lived and recovery/recolonisation will take place within an acceptable time frame, thus an acceptable in field risk can be concluded.

The off-field risks for NTA are therefore considered acceptable with the following mitigation measures:
-Wild apple; Pear; Chinese pear; Quince; Sour cherry; Sweet cherry; Peach; Nectarine; Apricot; Plum; Hazelnut; Walnut; Tobacco; Common osier; Purple willow – 2 x 25g a.s./ha:

- 90%-drift reducing nozzles are required when a no-spray buffer zone of 3 m is respected
- 75%-drift reducing nozzles are required when a no-spray buffer zone of 10 m is respected
- 50%-drift reducing nozzles are required when a no-spray buffer zone of 15 m is respected
- a no-spray buffer zone of 20 m is respected

- Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations- 1 x 40 g a.s./ha:

- 90%-drift reducing nozzles are required when a no-spray buffer zone of 3 m is respected
- 75%-drift reducing nozzles are required when a no-spray buffer zone of 10 m is respected
- 50%-drift reducing nozzles are required when a no-spray buffer zone of 15 m is respected
- a no-spray buffer zone of 20 m is respected

- Oilseed rape, maize, flax, hemp, soybean, sunflower, pumpkin, ornamentals < 50cm – 1 x 60 g a.s./ha:
  - 50%-drift reducing nozzles are required when a no-spray buffer zone of 1 m is respected
  - a no-spray buffer zone of 5 m is respected

For proposed uses in cereals and poppy the mitigation measures are not required.

9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Błąd! Nie można odnaleźć źródła odwołania.

The risk assessment was conducted according to the Guidance Document on Terrestrial Ecotoxicology (2002).

The risk from exposure to acetamiprid and relevant soil degradation products applied as LEPTOSAR 200 SL for all intended uses (risk envelope: 1 x 60 g a.s./ha for pumpkin) is indicated to be acceptable for the soil meso-/ macrofauna and soil microflora.

9.1.1.6 Toxicity data

9.1.1.7 Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with acetamiprid and relevant metabolites. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of LEPTOSAR 200 SL were not evaluated as part of the EU assessment of acetamiprid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
~~*Eisenia fetida*~~	~~acetamiprid~~	~~14 d, acute~~	~~LC_{50} = 1.52 mg/kg dw~~	~~Review Report, 2016~~
~~*Eisenia fetida*~~	~~Metabolite IM-1-2~~	~~14 d, acute~~	~~LC_{50} > 1000 mg/kg dw[2]~~	~~Review Report, 2016~~
~~*Eisenia fetida*~~	~~Metabolite IM-1-4~~	~~14 d, acute~~	~~LC_{50} > 1000 mg/kg dw[3]~~	~~Review Report, 2016~~
~~*Eisenia fetida*~~	~~Metabolite IC-0~~	~~14 d, acute~~	~~LC_{50} > 1000 mg/kg dw[4]~~	~~Review Report, 2016~~
~~*Eisenia fetida*~~	~~Metabolite IM-1-5~~	~~14 d, acute~~	~~LC_{50} > 1000 mg/kg dw[5]~~	~~Review Report, 2016~~
Eisenia fetida	Metabolite IM-1-5	Mixed into substrate 56 d, chronic	**NOEC= 62.5 mg/kg dw**	EFSA Journal 2016;14(11):4610;

Species	Substance	Exposure System	Results	Reference
			EC_{10}/LC_{10} = > 62.5 mg/kg dw	Review Report, 2016
Folsomia candida	Metabolite IM-1-5	Mixed into substrate / 28 d, chronic	$NOEC_{mortality}$ = 62.7 mg/kg dw soil **$NOEC_{reproduction}$ = 12.5 mg/kg dw soil** No EC values could be calculated as there were no effects below the highest tested value.	EFSA Journal 2016;14(11):4610; Review Report, 2016
~~*Eisenia fetida*~~	~~Representative formulation – Acetamiprid 20 SG~~	~~field study~~	~~Acetamiprid 20 SG at rates up to 80 g a.s./ha did not cause any adverse effects >50% on total earthworm abundance and biomass.~~	~~EFSA Journal 2016;14(11):4610; Review Report, 2016~~
~~*Folsomia candida*~~	~~Representative formulation – Acetamiprid 20 SG~~	~~Mixed into substrate 28 d, chronic 5% peat content~~	~~$NOEC_{mortality}$ = 0.49 mg a.s./kg soil d.w.~~ ~~LC_{10} = 0.82 mg a.s./kg soil d.w.~~ ~~**$NOEC_{reproduction}$ = 0.27 mg a.s./kg soil d.w.**~~ ~~EC_{10} = 0.47 mg a.s./kg soil d.w.~~	~~EFSA Journal 2016;14(11):4610; Review Report, 2016~~
~~*Hypoaspis aculeifer*~~	~~Representative formulation – Acetamiprid 20 SG~~	~~Mixed into substrate 14 d, chronic 5 % peat content~~	~~$NOEC_{mortality, reproduction}$ = 180 mg a.s./kg soil d.w.~~ ~~LC_{50} = > 180 mg a.s./kg soil d.w.~~ ~~**EC_{10} = 50.8 mg a.s./kg soil d.w.**~~	~~EFSA Journal 2016;14(11):4610; Review Report, 2016~~
Eisenia fetida	LEPTOSAR 200 SL	Mixed into substrate 56 d, chronic 10 % peat content	$LC_{50\ mortality}$ >3.08 mg a.s./kg soil d.w $NOEC_{mortality}$ = 1.71 mg a.s./kg soil d.w. $EC_{50,\ reproduction}$ > 3.08 mg a.s./kg soil d.w. $EC_{20,\ reproduction}$ =1.13 mg a.s./kg soil d.w.	Wołany, 2019a (Appendix 2)

Species	Substance	Exposure System	Results	Reference
			$EC_{10,\ reproduction}$ = 0.49 mg a.s./kg soil d.w. $NOEC_{reproduction}$ = 0.57 mg a.s./kg soil d.w.	
Folsomia candida	LEPTOSAR 200 SL	Mixed into substrate 28 d, chronic 5 % peat content	$LC_{50,\ mortality}$ = 0.44 mg a.s./kg soil d.w. $LC_{20,\ mortlaity}$ = 0.27 mg a.s./kg soil d.w. $LC_{10,}$ mortality = 0.21 mg a.s./kg soil d.w. **NOEC $_{mortality,\ reproduction}$ = 0.17 mg a.s./kg soil d.w.** $EC_{50,\ reproduction}$ = 0.51 mg a.s./kg soil d.w. $EC_{20,\ reproduction}$ =0.27 mg a.s./kg soil d.w. $EC_{10,\ repduction}$ = 0.19 mg a.s./kg soil d.w.	Wołany, 2019b (Appendix 2)
Hypoaspis aculeifer	LEPTOSAR 200 SL	Mixed into substrate 14 d, chronic 5 % peat content	$LC_{50,\ mortality}$ > 3.08 mg a.s./kg soil d.w. $LC_{20,\ mortality}$ > 3.08 mg a.s./kg soil d.w. $LC_{10,\ mortality}$ > 3.08 mg a.s./kg soil d.w. $NOEC_{\ mortality} \geq$ 3.08 mg a.s./kg soil d.w. $EC_{50,\ reproduction}$ > 3.08 mg a.s./kg soil d.w. $EC_{20,\ reproduction}$ =1.25 mg a.s./kg soil d.w. $EC_{10,\ reproduction}$ = 0.57 mg a.s./kg soil d.w. **NOEC $_{reproduction}$ = 0.57 mg a.s./kg soil d.w.**	Wołany, 2019c (Appendix 2)

Species	Substance	Exposure System	Results	Reference
Field studies				
-				
Litter bag test				
-				

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002 (not needed for acetamiprid and its metabolites since their log Pow is below 2)

9.1.1.8 Justification for new endpoints

No deviation from EU agreed endpoints.

9.1.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

9.1.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for acetamiprid, metabolite IM-1-2 and IC-0, but it is relevant for metabolite IM-1-4 and IM-1-5.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for pumpkin with application of 1 × 60 g ai/ha covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses in groups (see 9.1.2).

Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of LEPTOSAR 200 SL in pumpkin

Intended use	**Pumpkin 1× 60 g ai/ha**		
~~**Acute effects on earthworms**~~			
~~**Product/active substance**~~	~~**LC_{50} (ai or metabolite mg/kg dw)**~~	~~**PEC_{soil}* (mg/kg dw)**~~	~~**TER_a (criterion TER ≥ 10)**~~
~~acetamiprid~~	~~1.52~~	~~0.0320~~	~~47.5~~
~~Metabolite IM-1-2~~	~~1000~~	~~0.0190~~	~~52632~~
~~Metabolite IM-1-4~~	~~1000~~	~~0.0171*~~	~~58480~~
~~Metabolite IC-0~~	~~1000~~	~~0.0026~~	~~93458~~
~~Metabolite IM-1-5~~	~~1000~~	~~0.0107*~~	~~384615~~
Chronic effects on earthworms			

Product/active substance	**EC10/NOEC (ai or metabolite mg/kg dw)**	**PEC_{soil}* (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Metabolite IM-1-5	62.5	0.0107	5841
LEPTOSAR 200 SL	0.49	0.0320	15
Chronic effects on other soil macro- and mesofauna			
Product/active substance	**NOEC (ai or metabolite mg/kg dw)**	**PEC_{soil}* (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Metabolite IM-1-5 *(Folsomia candida)*	12.5	0.0107	1168
~~Representative formulation Acetamiprid 20 SG *(Folsomia candida)*~~	~~0.27~~	~~0.0320~~	~~8~~
LEPTOSAR 200 SL *(Folsomia candida)*	0.17	0.0320	5.3
~~Representative formulation Acetamiprid 20 SG *(Hypoaspis aculeifer)*~~	~~50.8~~	~~0.0320~~	~~1588~~
LEPTOSAR 200 SL *(Hypoaspis aculeifer)*	0.57	0.0320	18

TER values shown in bold fall below the relevant trigger.
* In case of acetamiprid, metabolite IM-1-2 and IC-0 PEC initial values are used for the risk assessment. In case of IM-1-4 and IM-1-5 PECaccum. are stated since DT_{50} soil for these substances is above 100 d.

9.1.2.2 Higher-tier risk assessment

Not relevant.

9.1.3 Overall conclusions

The risk from exposure to acetamiprid and relevant soil degradation products applied as LEPTOSAR 200 SL for all intended uses is indicated to be acceptable for the soil meso- and macrofauna.

Review Comments:

The long-term risks of LEPTOSAR 200 SL to soil meso- and macro-organisms were assessed from toxicity exposure ratios between toxicity endpoints and maximum PEC_{soil}. The relevant predicted environmental concentrations in soil (PEC_{soil}) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate).

Safe use of LEPTOSAR 200 SL was confirmed based on TER_{LT} calculations for active substance' metabolite and for formulation.

9.1.4 Toxicity data

Studies on effects soil microorganisms have been carried out with representative formulation containing acetamiprid. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on soil microorganisms of LEPTOSAR 200 SL were not evaluated as part of the EU assessment

of acetamiprid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.8-3: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
~~N-mineralisation~~	~~Representative formulation Acetamiprid 20 SG~~	~~28 d, aerobic~~	~~No negative effect > 25% at 28 d at 0.2 kg a.s./ha~~	~~EFSA Journal 2016;14(11):4610; Review Report, 2016~~
N-mineralisation	LEPTOSAR 200 SL	42 d, aerobic	No negative effect > 25% at 42 d at 0.16 mg a.s./kg dws	Wołany, 2019d (Appendix 2)

9.1.4.1 Justification for new endpoints

~~No deviation from EU agreed endpoints.~~ NA

9.1.5 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for pumpkin with application of 1 × 60 g ai/ha covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses in groups (see 9.1.2).

Table 9.8-4: Assessment of the risk for effects on soil micro-organisms due to the use of LEPTOSAR 200 SL in pumpkin

Intended use	**Pumpkin 1× 60 g ai/ha**		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**Application rate g ai/ha or PEC_{soil} (mg ai/kg dw)**	**Risk acceptable?**
~~Representative formulation Acetamiprid 20 SG~~	~~200 g ai /ha (at 28 d)~~	~~60 g ai/ha~~	~~yes~~
LEPTOSAR 200 SL	0.16 mg ai/kg dws (at 42 d)	0.0320 mg ai/kg dw	yes

9.1.6 Overall conclusions

The risk to soil microorganisms is acceptable since negligible effects on the nitrogen transformations are foreseen at higher levels than the calculated PEC soil values for the active when the intended use of pattern for the LEPTOSAR 200 SL is considered.

Review Comments:

LEPTOSAR 200 SL had no significant effect on soil micro-organisms at 0.16 mg a.s./kg dry soil. Based on it, can be concluded that LEPTOSAR 200 SL under field conditions, use at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

9.1.6.1 Effects on non-target terrestrial plants (KCP 10.6)

The risk assessment was based on the "Guidance Document on Terrestrial Ecotoxicology" (SANCO/10329/2002 rev.2 final, 2002).

The risk for non-target plants in the off-crop area is indicated to be acceptable.

In case of almost all crops recorded in the GAP table no risk mitigation measures need to be applied on the label.

The only exception are minor uses covered by the fruit crop scenario (apple, pear, cherry, peach, nectarine, apricot, plum, tree nuts, common osier, purple willow, tobacco and forest nurseries/Christmas trees plantations). In these cases **either 50% drift reduction or a 5 m buffer strip must be applied.**

9.1.6.2 No risk mitigation needed for almost all intended uses with exception of crops covered by scenario: fruit crops (early stage) with application of 2 × 25 g ai/ha and 1 × 50 g ai/ha

In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no spray buffer zones of 5 or 10 m; drift reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table.

Table 9.9-3: Risk assessment for non-target terrestrial plants due to the use of LEPTOSAR 200 SL in fruit crops[4] considering risk mitigation (in-field no-spray buffer zones, and drift reducing nozzles)

Intended use **Active substance/product** **Application rate (g/ha)** **MAF**		Fruit crops early stage[4] Acetamiprid/ LEPTOSAR 200 SL 1 × 50 g ai/ha and 2 × 25 g ai/ha 1 and 2			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g/ha)**	**$PER_{off\text{-}field}$ 50 % drift red. (g/ha)**	**$PER_{off\text{-}field}$ 75 % drift red. (g/ha)**	**$PER_{off\text{-}field}$ 90 % drift red. (g/ha)**
3	29.20%	14.600	7.300	3.650	1.460
5	19.89%	9.945	4.973	2.486	0.995
10	11.81%	5.905	2.953	1.476	0.591

Toxicity value ER_{50} = 60.5 g a.i./ha	TER criterion: TER ≥ 5			
3	**4.14**	8.29	16.58	41.44
5	6.08	12.17	24.33	60.83
10	10.25	20.49	40.98	102.46

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

9.1.7 Overall conclusions

The table above shows that the TER for the almost all use patterns of LEPTOSAR 200 SL are above the trigger of 5 even when no risk mitigation measures are applied.

In case of use in minor uses such as: apple, pear, cherry, peach, nectarine, apricot, plum, tree nuts, common osier, purple willow, tobacco and forest nurseries/Christmas trees plantations an acceptable risk is indicated when the risk mitigation measure (either 50% drift reduction or a 5 m buffer strip) is applied.

Overall, the risk for non-target plants for LEPTOSAR 200 SL is acceptable.

Review Comments:

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002).

Based on the risk assessment it can be concluded that the proposed use of LEPTOSAR 200 SL poses no unacceptable risk to non-target plants, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from LEPTOSAR 200 SL applications are not required for the protection of terrestrial non-target plants.

9.1.7.1 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

No further relevant data available and considered necessary.

9.1.8 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

Table 9.1-2: Critical use pattern of LEPTOSAR 200 SL grouped according to criterion

Grouping according to criterion			
Group	**Intended uses**	**Relevant parameters for grouping**	**Risk assessment**
1-94	Major and minor crops	- highest PEC soil for acetamiprid and relevant metabolites	- risk assessment for soil organisms
1-94	Major and minor crops	- highest PECsw for acetamiprid and relevant metabolites	- risk assessment for aquatic organisms
1-94	Major and minor crops	- highest shortcut values	- risk assessment for birds and

~~Grouping according to criterion~~			
~~Group~~	~~Intended uses~~	~~Relevant parameters for grouping~~	~~Risk assessment~~
			~~mammals~~
~~1-94~~	~~Major and minor crops~~	~~-highest dosage rate~~	~~- risk assessment for bees and other arthropods~~

Review comments:

The grouping of the intended uses of LEPTOSAR 200 SL provided by the Applicant in Table 9.1-2 was to very general, therefore for clarity of the assessment zRMS updated critical GAP.
As application of product to fruiting vegetables is limited to greenhouses, additional assessment was not required.

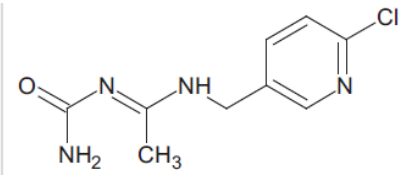
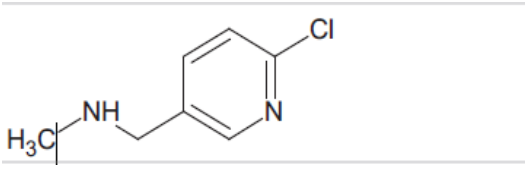
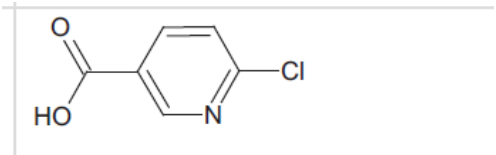
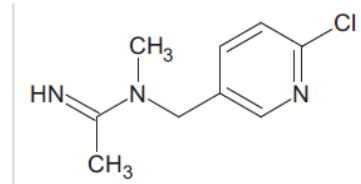
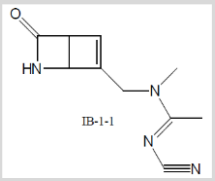
Group	Intended uses	relevant use parameters for grouping	relevant parameter or value
Terrestrial vertebrates (Birds and Mammals; **9.2** and **9.3**)	According to GAP	Scenarios according to EFSA Birds and Mammals Guidance (2009)	Crop, application rate, number of applications, timing criterion
Aquatic organisms (**9.5**)	According to GAP	Crops according to FOCUS surface water guidance (2015)[1]	FOCUS modelling**,** for detalis see Part B 8
Bees (**9.6**)	Generic risk envelope covering all product uses	Risk assessments are based on the maximum single application rate	Maximum single application rate
Terrestrial non-target arthropods other than bees (**9.7**)	According to GAP In-field	In-field and off-field risk assessments are based on the maximum application rate for each type of crops	Application rate and number of uses
	According to GAP Off-field		Crop type (height), application rate and number of uses
Soil meso- and macrofauna / soil microorganisms (**9.8** and **9.9**)	Generic risk envelope covering all product uses	Risk assessments are based on the application rate of 1 x 0.06 kg s.a./ha in Pumpkin	Worst case PECsoil value taken from Section 8 (Environmental Fate)
Non-target terrestrial plants (**9.10**)	According to GAP	Risk assessments are based on the maximum single application rate for each type of crops	Application rate and drift rate

9.1.9 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of LEPTOSAR 200 SL is indicated in the table.

[1] FOCUS (2015): Generic guidance for FOCUS surface water Scenarios. Version 1.4.

Table 9.1-3 Metabolites of acetamiprid

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
IM-1-2		240.69	55% in soil	Soil- yes Aquatic - yes
IM-1-4		156.62	72% in soil	Soil- yes Aquatic - yes
IC-0		157.55	11.3% in soil	Soil- yes Aquatic - yes
IM-1-5		197.67	20% (in calcareous soils only)	Soil- yes Aquatic - yes
IB-1-1		204.23	Water/Sediment: > 10 % of a.s.	Yes

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with acetamiprid and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on birds of LEPTOSAR 200 SL were not evaluated as part of the EU assessment of acetamiprid. However, the provision of further data on the formulation LEPTOSAR 200 SL is not considered essential, because toxicity of LEPTOSAR 200 SL can be predicted on the basis of the data for the active substance.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
Anas platyrhnchos	acetamiprid		LD_{50} = 98	EFSA, 2016. Conclusion on

Species	Substance	Exposure System	Results	Reference
(mallard duck)		Acute		the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610, 91 pp. doi:10.2903/j.efsa.2016.4610
Colinus virginianus (bobwhite quail	acetamiprid	Acute	LD_{50} >100	
Poephila guttata (zebra finch)	acetamiprid	Acute	LD_{50} = 5.7	
Geometric mean	acetamiprid	Acute	**LD_{50} = 38.2**	
		Long-term	**LD_{50}/10 = 3.8**	
Anas platyrhynchos (mallard duck)	acetamiprid	Long-term	NOAEL = 9.5	

Values in **bold** to be considered in Risk Asessment

9.2.1.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables. Exposure via directly sprayed diet is not relevant for the indoor use in tomatoes.

Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of LEPTOSAR 200 SL in maize

Intended use	Maize				
Active substance/product	acetamiprid				
Application rate (g/ha)	1 × 60				
Acute toxicity (mg/kg bw)	38.2				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
BBCH > 40	Medium granivorous bird “gamebird”	1.6	1.0	0.10	382
BBCH > 40	Small omnivorous bird “lark”	6.0	1.0	0.36	106
BBCH > 40	Medium herbivorous/granivorous bird “pigeon”	13.9	1.0	0.83	46
BBCH ≥ 20	Small insectivorous bird “wagtail”	12.6	1.0	0.76	50.3
Reprod. toxicity (mg/kg bw/d)	3.82				

TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
BBCH > 40	Medium granivorous bird “gamebird”	0.8	0.53	0.03	150
BBCH > 40	Small omnivorous bird “lark”	2.7	0.53	0.09	42
BBCH > 40	Medium herbivorous/granivorous bird “pigeon”	5.7	0.53	0.18	21
BBCH ≥ 20	Small insectivorous bird “wagtail”	4.8	0.53	0.15	25.5

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-3: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of LEPTOSAR 200 SL in cereals

Intended use	Cereals (according to the GAP BBCH≥30)				
Active substance/product	acetamiprid				
Application rate (g/ha)	1 × 40				
Acute toxicity (mg/kg bw)	38.2				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
~~Cereals BBCH 10 – 29~~	~~Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods~~	~~24.0~~	1.0	~~0.96~~	~~39.8~~
Cereals BBCH 30 -39	Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	12.0		0.48	79.6
~~Cereals Early (shoots) autumn-winter BBCH 10-29~~	~~Large herbivorous bird "goose" Grass + cereals 100% cereal shoots~~	~~30.5~~		~~1.22~~	~~31.3~~
BBCH > 40	Small omnivorous bird “lark”	7.2		0.29	132.6
Reprod. toxicity (mg/kg bw/d)	3.82				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals BBCH ≥ 40	Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	0.53	0.07	54.6
~~Cereals BBCH 10 – 29~~	~~Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods~~	~~10.9~~		~~0.24~~	~~16.5~~
Cereals BBCH 30 -39	Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	5.4		0.12	33.4
~~Cereals Early~~	~~Large herbivorous bird "goose" Grass + cereals~~	~~16.2~~		~~0.36~~	~~10.5~~

~~(shoots) autumn-winter BBCH 10-29~~	~~100% cereal shoots~~				

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-4: First-tier assessment of the acute and long-term/reproductive risk for birds due to the ~~multiple~~ use of LEPTOSAR 200 SL in oilseed rape

Intended use	Oilseed rape *(also: flax, common hemp, ~~soybean,~~ opium poppy)*				
Active substance/product	acetamiprid				
Application rate (g/ha)	60				
Acute toxicity (mg/kg bw)	38.2				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Oilseed rape BBCH 10 - 29	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	24.0	1	1.44	26.5
Oilseed rape BBCH 20 - 29	Small insectivorous bird “wagtail” ground invertebrates with interception 100% soil dwelling invertebrates	7.7		0.46	82.7
Oilseed rape BBCH 20 - 29	medium herbivorous/granivorous bird "pigeon" Comby to be calculated 50 % crop leaves 50 % weed seeds	4.0		0.24	159.2
Oilseed rape BBCH 30 - 39	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	7.2		0.43	88.4
Oilseed rape BBCH 30 - 39	medium herbivorous/granivorous bird "pigeon" Comby to be calculated 50 % crop leaves 50 % weed seeds	2.4		0.144	265.3
Oilseed rape late – late (with seeds) (BBCH 30-99)	Small insectivorous bird "dunnock) ground invertebrates with interception 100% soil dwelling invertebrates	7.4		0.44	86.0
Oilseed rape BBCH ≥ 40	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	6.0		0.36	106.1
Oilseed rape BBCH 10 - 19	Small insectivorous bird “wagtail” ground invertebrates without interception 100% soil dwelling invertebrates	10.9		0.65	58.4
Oilseed rape BBCH 10 - 19	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% crop shoots	55.6		3.34	11.5
Oilseed rape BBCH 10 - 19	Large herbivorous bird “goose”	39.0		2.34	16.3
Oilseed rape BBCH ≥ 40	medium herbivorous/granivorous bird "pigeon"	2.0		0.12	318.3

Reprod. toxicity (mg/kg bw/d)	3.82				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Oilseed rape BBCH 10 - 29	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9	0.53	0.35	11.0
Oilseed rape BBCH 20 - 29	Small insectivorous bird “wagtail” ground invertebrates with interception 100% soil dwelling invertebrates	2.8		0.09	42.9
Oilseed rape BBCH 20 - 29	medium herbivorous/granivorous bird "pigeon" Comby to be calculated 50 % crop leaves 50 % weed seeds	3.5		0.11	34.3
Oilseed rape BBCH 30 - 39	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3		0.10	36.4
Oilseed rape BBCH 30 - 39	medium herbivorous/granivorous bird "pigeon" Comby to be calculated 50 % crop leaves 50 % weed seeds	1.1		0.03	109.2
Oilseed rape late – late (with seeds) (BBCH 30-99)	Small insectivorous bird "dunnock) ground invertebrates with interception 100% soil dwelling invertebrates	2.7		0.09	44.5
Oilseed rape BBCH ≥ 40	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	2.7		0.09	44.5
Oilseed rape BBCH 10 - 19	Small insectivorous bird “wagtail” ground invertebrates without interception 100% soil dwelling invertebrates	5.9		0.19	20.4
Oilseed rape BBCH 10 - 19	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% crop shoots	22.7		0.72	5.3
Oilseed rape BBCH 10 - 19	Large herbivorous bird “goose”	15.9	0.53	0.51	7.5
Oilseed rape BBCH ≥ 40	medium herbivorous/granivorous bird "pigeon"	0.9		0.03	127.3

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-5: First-tier assessment of the acute and long-term/reproductive risk for birds due to the multiple use of LEPTOSAR 200 SL in orchard

Intended use	Orchard (according to the GAP BBCH ≥50) (*also*: *apple, pear, quince, cherry, peach, plum, hazelnut, walnut, ~~tabacco~~, common osier, purple willow)*
Active substance/product	acetamiprid
Application rate (g/ha)	25
Acute toxicity (mg/kg bw)	38.2

TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchard Crop directed application BBCH ≥ 40	Small granivorous bird "finch" Small seeds 100% seeds	8.2	1.4	0.29	133.1
Orchard Crop directed application BBCH ≥ 40	Small insectivorous/worm feeding species “thrush” ground invertebrates with interception 100% soil dwelling invertebrates	2.2		0.08	496.1
~~Orchard Crop directed application BBCH 10—19~~	~~Small granivorous bird "finch" Small seeds 100% seeds~~	~~21.9~~		~~0.77~~	~~49.8~~
~~Orchard Crop directed application BBCH 10—19~~	~~Small insectivorous/worm feeding species “thrush” ground invertebrates with interception 100% soil dwelling invertebrates~~	~~5.9~~		~~0.21~~	~~185.0~~
~~Orchard Crop directed application BBCH 20—39~~	~~Small granivorous bird "finch" Small seeds 100% seeds~~	~~16.4~~		~~0.57~~	~~66.6~~
~~Orchard Crop directed application BBCH 20—39~~	~~Small insectivorous/worm feeding species “thrush” ground invertebrates with interception 100% soil dwelling invertebrates~~	~~4.4~~		~~0.15~~	~~248.1~~
Orchard Spring Summer.	Small insectivorous bird “tit” Foliar insects 100% foliar insects	46.8		1.64	23.3
Reprod. toxicity (mg/kg bw/d)	3.82				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchard Crop directed application BBCH ≥ 40	Small granivorous bird "finch" Small seeds 100% seeds	3.8	1.6 x 0.53	0.08	47.4
Orchard Crop directed application BBCH ≥ 40	Small insectivorous/worm feeding species “thrush” ground invertebrates with interception 100% soil dwelling invertebrates	0.8		0.02	225.2
~~Orchard Crop directed application BBCH 10—19~~	~~Small granivorous bird "finch" Small seeds 100% seeds~~	~~10.1~~		~~0.21~~	~~17.8~~
~~Orchard Crop directed application BBCH 10—19~~	~~Small insectivorous/worm feeding species “thrush” ground invertebrates with interception 100% soil dwelling invertebrates~~	~~2.1~~		~~0.04~~	~~85.8~~
~~Orchard Crop directed~~	~~Small granivorous bird "finch" Small seeds 100% seeds~~	~~7.6~~		~~0.16~~	~~23.7~~

~~application BBCH 20 – 39~~					
~~Orchard Crop directed application BBCH 20 – 39~~	~~Small insectivorous/worm feeding species "thrush" ground invertebrates with interception 100% soil dwelling invertebrates~~	~~1.6~~		~~0.03~~	~~112.6~~
Orchard Spring Summer.	Small insectivorous bird "tit" Foliar insects 100% foliar insects	18.2		0.39	9.9

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-6: First-tier assessment of the acute and long-term/reproductive risk for birds due to the ~~multiple~~ use of LEPTOSAR 200 SL in ornamentals and nursery.

Intended use	Ornamental and nursery (*Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations;Christmas trees grown on plantations)*				
Active substance/product	acetamiprid				
Application rate (g/ha)	60 (covers propose dose rate of 40 g a.s./ha)				
Acute toxicity (mg/kg bw)	38.2				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Ornamentals and nursery Application to plant	Small insectivorous bird "tit" Foliar insects 100% foliar insects	46.8	1	2.81	16.3
Ornamentals and nursery Application to plant – exposure to underlying ground	Small insectivorous/worm feeding species "thrush" ground invertebrates with interception 100% soil dwelling invertebrates	7.4		0.44	103.2
Reprod. toxicity (mg/kg bw/d)	3.82				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Ornamentals and nursery Application to plant	Small insectivorous bird "tit" Foliar insects 100% foliar insects	18.2	0.53	0.58	7.9
Ornamentals and nursery Application to plant – exposure to underlying ground	Small insectivorous/worm feeding species "thrush" ground invertebrates with interception 100% soil dwelling invertebrates	2.7		0.09	53.4

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-7: First-tier assessment of the acute and long-term/reproductive risk for birds due to the ~~multiple~~ use of LEPTOSAR 200 SL in sunflower.

Intended use	Sunflower				
Active substance/product	acetamiprid				
Application rate (g/ha)	60 (covers propose dose rate of 50 g a.s./ha)				
Acute toxicity (mg/kg bw)	38.2				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Sunflower Early (Germination/ leaf development) BBCH 00-19	Small insectivorous bird “wagtail” Combination (ground invertebrates without interception) 50% ground arthropods. 50% foliar arthropods	26.8	1	1.61	23.8
Sunflower Early (Germination/ leaf development) BBCH 00-19	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	24.0		1.44	26.5
Sunflower Late (Flowering. seed ripening) BBCH 61-92	Small granivorous/insectivorous bird “bunting” Small seeds 100% crop seeds	21.7		1.30	29.3
Reprod. toxicity (mg/kg bw/d)	3.82				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Sunflower Early (Germination/ leaf development) BBCH 00-19	Small insectivorous bird “wagtail” Combination (ground invertebrates without interception) 50% ground arthropods. 50% foliar arthropods	11.3	0.53	0.36	10.6
Sunflower Early (Germination/ leaf development) BBCH 00-19	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9		0.35	11.0
Sunflower Late (Flowering. seed ripening) BBCH 61-92	Small granivorous/insectivorous bird “bunting” Small seeds 100% crop seeds	10.0		0.32	12.0

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-8: First-tier assessment of the acute and long-term/reproductive risk for birds due to the ~~multiple~~ use of LEPTOSAR 200 SL in Pumpkin.

Intended use	Fruiting vegetable (according to the GAP BBCH ≥50)				
Active substance/product	acetamiprid				
Application rate (g/ha)	60				
Acute toxicity (mg/kg bw)	38.2				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Fruiting vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	25.2	1	1.51	25.3
Fruiting vegetables BBCH ≥ 50	Small granivorous bird "finch" Small seeds 100% weed seeds	7.4		0.44	86.0
Fruiting vegetables BBCH ≥ 50	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	7.2		0.43	88.4
~~Fruiting vegetables BBCH 10 – 49~~	~~Small granivorous bird "finch" Small seeds 100% weed seeds~~	~~24.7~~		~~1.48~~	~~25.8~~
~~Fruiting vegetables BBCH 10 – 49~~	~~Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods~~	~~24.0~~		~~1.44~~	~~26.5~~
Reprod. toxicity (mg/kg bw/d)	3.82				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Fruiting vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	9.7	0.53	0.31	12.4
Fruiting vegetables BBCH ≥ 50	Small granivorous bird "finch" Small seeds 100% weed seeds	3.4		0.11	35.3
Fruiting vegetables BBCH ≥ 50	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3		0.10	36.4
~~Fruiting vegetables BBCH 10 – 49~~	~~Small granivorous bird "finch" Small seeds 100% weed seeds~~	~~11.4~~		~~0.36~~	~~10.5~~
~~Fruiting vegetables BBCH 10 – 49~~	~~Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods~~	~~10.9~~		~~0.35~~	~~11.0~~

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-9: First-tier assessment of the acute and long-term/reproductive risk for birds due to the multiple use of LEPTOSAR 200 SL in Tobacco.

Intended use	Maize (covers tobacco)				
Active substance/product	acetamiprid				
Application rate (g/ha)	2 x 25				
Acute toxicity (mg/kg bw)	38.2				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
BBCH 30-39	Medium granivorous bird “gamebird”	3.3	1.4	0.12	318.3
BBCH ≥ 40	Medium granivorous bird “gamebird”	1.6		0.06	636.7
BBCH 30-39	Small omnivorous bird “lark”	12.0		0.42	90.9
BBCH ≥ 40	Small omnivorous bird “lark”	6.0		0.21	181.9
BBCH 30-39	Medium herbivorous/granivorous bird “pigeon”	27.8		0.97	39.4
BBCH ≥ 40	Medium herbivorous/granivorous bird “pigeon”	13.9		0.49	78.8
BBCH ≥ 20	Small insectivorous bird “wagtail”	12.6		0.44	86.8
Reprod. toxicity (mg/kg bw/d)	3.82				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
BBCH 30-39	Medium granivorous bird “gamebird”	1.5	1.6 x 0.53	0.03	127.3
BBCH ≥ 40	Medium granivorous bird “gamebird”	0.8		0.02	191
BBCH 30-39	Small omnivorous bird “lark”	5.4		0.11	34.7
BBCH ≥ 40	Small omnivorous bird “lark”	2.7		0.06	63.7
BBCH 30-39	Medium herbivorous/granivorous bird “pigeon”	11.4		0.24	15.9
BBCH ≥ 40	Medium herbivorous/granivorous bird “pigeon”	5.7		0.12	31.8
BBCH ≥ 20	Small insectivorous bird “wagtail”	4.8		0.10	38.2

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.22-10: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of LEPTOSAR 200 SL in soybean (pulses)

Intended use	Pulses (soybean) BBCH 11-19 and 61-65				
Active substance/product	acetamiprid				
Application rate (g/ha)	60				
Acute toxicity (mg/kg bw)	38.2				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Pulses BBCH 10-49	Small granivorous bird "finch"	24.7	1	1.48	25.8
Pulses BBCH ≥ 50	Small granivorous bird "finch"	7.4	1	0.44	86.8
Pulses BBCH 10-49	Small omnivorous bird "lark"	24.0	1	1.44	26.5
Pulses BBCH ≥ 50	Small omnivorous bird "lark"	7.2	1	0.43	88.8
Pulses BBCH 10 - 19	Medium herbivorous/granivorous bird "pigeon"	55.6	1	3.34	11.4
Pulses BBCH 10 - 19	Small insectivorous bird "wagtail"	26.8	1	1.61	23.7
Pulses BBCH ≥20	Small insectivorous bird "wagtail"	25.2	1	1.51	25.3
Reprod. toxicity (mg/kg bw/d)	3.82				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Pulses BBCH 10-49	Small granivorous bird "finch"	11.4	1 x 0.53	0.36	10.6
Pulses BBCH ≥ 50	Small granivorous bird "finch"	3.4	1 x 0.53	0.11	34.7
Pulses BBCH 10-49	Small omnivorous bird "lark"	10.9	1 x 0.53	0.35	10.9
Pulses BBCH ≥ 50	Small omnivorous bird "lark"	3.3	1 x 0.53	0.10	38.2
Pulses BBCH 10 - 19	Medium herbivorous/granivorous bird "pigeon"	22.7	1 x 0.53	0.72	5.3
Pulses BBCH 10 - 19	Small insectivorous bird "wagtail"	11.3	1 x 0.53	0.36	10.6
Pulses BBCH ≥20	Small insectivorous bird "wagtail"	9.7	1 x 0.53	0.31	12.3

9.2.2.2 Higher-tier risk assessment

Not required

9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is

conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Leaf scenario

Since LEPTOSAR 200 SL is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

To achieve a concise risk assessment. the risk envelope approach is applied. Here. the assessment for the use in maize also covers the risk for birds from all other intended uses (see 9.1.8).

With a K(f)oc of 100.2 (geometric mean), acetamiprid belongs to the group of less sorptive substances

Effective application rate (g/ha)	=	60		
Acute toxicity (mg/kg bw)	=	38.2	quotient =	1.57
Reprod. toxicity (mg/kg bw/d)	=	3.82	quotient =	15.7

No specific TER calculation for puddle scenario is necessary.
The above ratios are below the trigger value of 50 indicating an acceptable risk to birds via drinking water contaminated from the proposed uses of LEPTOSAR 200 SL

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of acetamiprid amounts to 0.80 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating birds via secondary poisoning

Not required.

Risk assessment for fish-eating birds via secondary poisoning

Not required.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.4 Overall conclusions

The risk for birds arising from acute and long-term exposure to LEPTOSAR 200 SL is acceptable. Moreover, the risk for birds due to uptake of contaminated drinking water is also acceptable.

Review Comments:

The acute and chronic risks of LEPTOSAR 200 SL to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from study with active ingredient, and maximum residues occurring on food items. No acute toxicity test with the formulation was required.

All TER values exceed the relevant triggers indicating that LEPTOSAR 200 SL does not pose an unacceptable risk to birds following applications according to recommended use pattern.

Evaluation of exposing to birds through the drinking water demonstrated the acceptable risk. The risk to earthworm- and fish-eating animals from secondary poisoning is not required.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with acetamiprid. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of LEPTOSAR 200 SL were not evaluated as part of the EU assessment of acetamiprid.
However, the provision of further data on the formulation LEPTOSAR 200 SL is not considered essential, because toxicity of LEPTOSAR 200 SL can be predicted on the basis of the data for the active substance.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	acetamiprid	Acute	LD_{50} = 146 mg/kg bw	EFSA, 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610, 91 pp. doi:10.2903/j.efsa.2016.4610
Rat	acetamiprid	Long - term	NOAEL = 2.5 mg/kg bw/d	

9.3.1.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

9.3.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of LEPTOSAR 200 SL in maize

Intended use	maize				
Active substance/product	acetamiprid				
Application rate (g/ha)	60				
Acute toxicity (mg/kg bw)	146				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Maize BBCH ≥ 20	Small insectivorous mammal "shrew"	5.4	1.0	0.32	456.2
Maize BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals All maize shoots + later grass	34.1	1.0	2.05	71.4
Maize BBCH ≥ 40	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	4.3	1.0	0.26	565.9
Reprod. toxicity (mg/kg bw/d)	2.5				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize BBCH ≥ 20	Small insectivorous mammal "shrew"	1.9	0.53	0.06	41.4
Maize BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals All maize shoots + later grass	18.1	0.53	0.58	**4.3**
Maize BBCH ≥ 40	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	1.9	0.53	0.06	41.4

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-3: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of LEPTOSAR 200 SL in cereals

Intended use	Cereals (according to the GAP BBCH≥30)				
Active substance/product	acetamiprid				
Application rate (g/ha)	1 × 40				
Acute toxicity (mg/kg bw)	146				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods	5.4	1.0	0.22	675.9
Cereals BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	40.9	1.0	1.64	89.2
Cereals BBCH ≥ 40	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	5.2	1.0	0.21	701.9
~~Cereals BBCH 10-29~~	~~Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods~~	~~17.2~~	~~1.0~~	~~0.69~~	~~212.2~~
Cereals BBCH 30 - 39	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	8.6	1.0	5.84	424.4
~~Cereals Early (shoots)~~	~~Large herbivorous mammal “lagomorph” Grass + cereals 100% cereal shoots~~	~~42.1~~	~~1.0~~	~~1.69~~	~~86.7~~
Reprod. toxicity (mg/kg bw/d)	2.5				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods	1.9	0.53	0.04	62.1
Cereals BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	21.7	0.53	0.46	5.4
Cereals BBCH ≥ 40	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	0.53	0.05	51.3
~~Cereals BBCH 10-29~~	~~Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods~~	~~7.8~~	~~0.53~~	~~0.17~~	~~15.1~~
Cereals BBCH	Small omnivorous mammal “mouse”	3.9	0.53	0.08	30.2

30 - 39	Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods				
~~Cereals Early (shoots)~~	~~Large herbivorous mammal "lagomorph" Grass + cereals 100% cereal shoots~~	~~22.3~~	~~0.53~~	~~0.47~~	~~5.3~~

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-4: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the ~~multiple~~ use of LEPTOSAR 200 SL in oilseed rape

Intended use	Oilseed rape **(also:** ***Flax, common hemp, ~~soybean~~, opium poppy)***				
Active substance/product	acetamiprid				
Application rate (g/ha)	60				
Acute toxicity (mg/kg bw)	146				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Oilseed rape All season	Large herbivorous mammal "lagomorph" Non-grass herbs 100% crop leaves	35.1	1	2.1	69.3
Oilseed rape BBCH ≥ 20	Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods	5.4	1	0.32	450.6
Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	34.1	1	2.05	71.4
Oilseed rape BBCH ≥ 40	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	4.3	1	0.28	565.9
Oilseed rape BBCH 10-29	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	17.2	1	1.03	141.7
Oilseed rape BBCH 30-39	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	5.2	1	0.31	467.9
Oilseed rape BBCH 10 - 19	Small insectivorous mammal "shrew" ground dwelling invertebrates without interception 100% ground arthropods	7.6	1	0.46	320.2
Reprod. toxicity (mg/kg bw/d)	2.5				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Oilseed rape All season	Large herbivorous mammal "lagomorph" Non-grass herbs 100% crop leaves	14.3	0.53	0.45	5.5

Oilseed rape BBCH ≥ 20	Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods	1.9	0.53	0.06	41.4
Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	18.1	0.53	0.58	**4.3**
Oilseed rape BBCH ≥ 40	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	1.9	0.53	0.06	41.4
Oilseed rape BBCH 30 - 39	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	0.53	0.07	34.2
Oilseed rape BBCH 10-29	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	0.53	0.25	10.0
Oilseed rape BBCH 10 - 19	Small insectivorous mammal "shrew" ground dwelling invertebrates without interception 100% ground arthropods	4.2	0.53	0.13	18.7

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-5: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the multiple use of LEPTOSAR 200 SL in orchard.

Intended use	Orchard (according to the GAP BBCH ≥50) (***apple, pear, quince, cherry, peach, plum, hazelnut, walnut~~, tabacco~~, common osier, purple willow)***
Active substance/product	acetamiprid
Application rate (g/ha)	25
Acute toxicity (mg/kg bw)	146
TER criterion	10

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchard Application crop directed BBCH ≥ 40	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	10.5	1.4	0.37	397.3
Orchard Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	40.9	1.4	1.43	102.0
Orchard Application crop directed BBCH ≥ 40	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	5.2	1.4	0.18	802.2
~~Orchard Application crop directed BBCH 10–19~~	~~Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs~~	~~28.1~~	~~1.4~~	~~0.98~~	~~148.4~~

~~Orchard Application crop directed BBCH 10–19~~	~~Small herbivorous mammal "vole Grass + cereals 100% grass~~	~~109.2~~	~~1.4~~	~~3.82~~	~~38.2~~
~~Orchard Application crop directed BBCH 10–19~~	~~Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods~~	~~13.8~~	~~1.4~~	~~0.48~~	~~302.3~~
~~Orchard Application crop directed BBCH 20–40~~	~~Large herbivorous mammal "lagomorph" Non-grass herbs 100% Non-grass herbs~~	~~21.1~~	~~1.4~~	~~0.74~~	~~197.7~~
~~Orchard Application crop directed BBCH 20–40~~	~~Small herbivorous mammal "vole Grass + cereals 100% grass~~	~~81.9~~	~~1.4~~	~~2.87~~	~~50.9~~
~~Orchard Application crop directed BBCH 20–40~~	~~Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods~~	~~10.3~~	~~1.4~~	~~0.36~~	~~405.0~~
Orchard Fruit stage BBCH 71-79 currants	Frugivorous mammal "dormouse" larger fruits 100% fruit	47.9	1.4	1.68	87.1
Reprod. toxicity (mg/kg bw/d)	2.5				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchard Application crop directed BBCH ≥ 40	Large herbivorous mammal "lagomorph" Non-grass herbs 100% Non-grass herbs	4.3	1.6 x 0.53	0.09	27.4
Orchard Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	21.7	1.6 x 0.53	0.46	5.4
Orchard Application crop directed BBCH ≥ 40	Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	1.6 x 0.53	0.05	51.3
~~Orchard Application crop directed BBCH 10–19~~	~~Large herbivorous mammal "lagomorph" Non-grass herbs 100% Non-grass herbs~~	~~11.5~~	~~1.6 x 0.53~~	~~0.24~~	~~10.3~~
~~Orchard Application crop directed BBCH 10–19~~	~~Small herbivorous mammal "vole Grass + cereals 100% grass~~	~~57.8~~	~~1.6 x 0.53~~	~~1.23~~	~~2.0~~
~~Orchard Application crop directed BBCH 10–19~~	~~Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods~~	~~6.2~~	~~1.6 x 0.53~~	~~0.13~~	~~19.0~~
~~Orchard~~	~~Large herbivorous mammal~~	~~8.6~~	~~1.6 x 0.53~~	~~0.18~~	~~13.7~~

~~Application crop directed BBCH 20- 40~~	~~"lagomorph" Non-grass herbs 100% Non-grass herbs~~				
~~Orchard Application crop directed BBCH 20- 40~~	~~Small herbivorous mammal "vole Grass + cereals 100% grass~~	~~43.4~~	~~1.6 x 0.53~~	~~0.92~~	~~2.7~~
~~Orchard Application crop directed BBCH 20- 40~~	~~Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods~~	~~4.7~~	~~1.6 x 0.53~~	~~0.10~~	~~25.1~~
Orchard Fruit stage BBCH 71-79 currants	Frugivorous mammal "dormouse" larger fruits 100% fruit	22.7	1.6 x 0.53	0.48	5.2

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-6: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the multiple use of LEPTOSAR 200 SL in ornamentals and nursery.

Intended use	Ornamentals and nursery
Active substance/product	acetamiprid
Application rate (g/ha)	~~50~~ 40
Acute toxicity (mg/kg bw)	146
TER criterion	10

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Ornamentals and nursery Application crop directed BBCH ≥ 50	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	8.6	1	~~0.43~~ 0.34	~~339.5~~ 429.4
Ornamentals and nursery Application crop directed BBCH 10 - 49	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	17.2	1	~~0.86~~ 0.69	~~169.8~~ 211.6
Ornamentals and nursery Application to plant – exposure to underlying ground	Small insectivorous mammal "shrew" Ground dwelling invertebrates with interception 100% ground arthropods	5.4	1	~~0.27~~ 0.22	~~540.7~~ 663.6
Ornamentals and nursery BBCH ≥ 50	Small herbivorous mammal "vole Grass + cereals 100% grass	68.2	1	~~3.41~~ 2.73	~~42.8~~ 53.5
Ornamentals and nursery BBCH 40 - 49	Small herbivorous mammal "vole Grass + cereals 100% grass	136.4	1	~~6.82~~ 5.46	~~21.4~~ 26.7

Reprod. toxicity (mg/kg bw/d)	2.5				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Ornamentals and nursery Application crop directed BBCH ≥ 50	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	3.9	0.53	~~0.10~~ 0.08	~~24.2~~ 31.3
Ornamentals and nursery Application crop directed BBCH 10 - 49	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	0.53	~~0.21~~ 0.16	~~12.1~~ 15.6
Ornamentals and nursery Application to plant – exposure to underlying ground	Small insectivorous mammal “shrew” Ground dwelling invertebrates with interception 100% ground arthropods	1.9	0.53	~~0.50~~ 0.04	~~49.7~~ 62.5
Ornamentals and nursery BBCH ≥ 50	Small herbivorous mammal "vole Grass + cereals 100% grass	36.1	0.53	~~0.96~~ 0.76	~~**2.6**~~ **3.2**
Ornamentals and nursery BBCH 40 - 49	Small herbivorous mammal "vole Grass + cereals 100% grass	72.3	0.53	~~1.92~~ 1.53	~~**1.3**~~ **1.6**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-7: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the multiple use of LEPTOSAR 200 SL in sunflower

Intended use	Sunflower				
Active substance/product	acetamiprid				
Application rate (g/ha)	~~60~~ 50				
Acute toxicity (mg/kg bw)	146				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Sunflower BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	5.4	1	~~0.32~~ 0.27	~~450.6~~ 540.7
Sunflower BBCH ≥ 40	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	8.8	1	~~0.53~~ 0.44	~~276.5~~ 331.8
Sunflower BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	34.1	1	~~2.05~~ 1.71	~~71.4~~ 85.4
Sunflower	Small omnivorous mammal “mouse”	4.3	1	~~0.26~~	~~565.9~~

BBCH ≥ 40	Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods			0.22	663.6
Sunflower BBCH 10 - 19	Small insectivorous mammal “shrew” ground dwelling invertebrates without interception 100% ground arthropods	7.6	1	~~0.46~~ 0.38	~~320.2~~ 384.2
Sunflower BBCH 10 - 19	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	35.1	1	~~2.1~~ 1.76	~~69.3~~ 82.9
Sunflower BBCH 10 - 19	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	17.2	1	~~1.03~~ 0.86	~~141.5~~ 169.8
Sunflower BBCH 20 - 39	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	17.6	1	~~1.06~~ 0.88	~~138.3~~ 165.9
Sunflower BBCH 20 - 39	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	8.6	1	~~0.52~~ 0.43	~~282.9~~ 339.5
Reprod. toxicity (mg/kg bw/d)	2.5				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Sunflower BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	1.9	0.53	~~0.06~~ 0.05	~~41.4~~ 50.0
Sunflower BBCH ≥ 40	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	3.6	0.53	~~0.11~~ 0.10	~~21.8~~ 25.0
Sunflower BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	18.1	0.53	~~0.58~~ 0.48	~~**4.3**~~ 5.2
Sunflower BBCH ≥ 40	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	1.9	0.53	~~0.06~~ 0.05	~~41.4~~ 50.0
Sunflower BBCH 10 - 19	Small insectivorous mammal “shrew” ground dwelling invertebrates without interception 100% ground arthropods	4.2	0.53	~~0.13~~ 0.11	~~18.7~~ 22.7
Sunflower BBCH 10 - 19	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	14.3	0.53	~~0.45~~ 0.38	~~5.5~~ 6.6
Sunflower BBCH 10 - 19	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	0.53	~~0.25~~ 0.21	~~10.1~~ 11.9
Sunflower BBCH 20 - 39	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	7.2	0.53	~~0.23~~ 0.19	~~10.9~~ 13.3
Sunflower	Small omnivorous mammal “mouse”	3.9	0.53	~~0.12~~	~~20.2~~

BBCH 20 - 39	Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods			0.10	25.0

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-8: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the multiple use of LEPTOSAR 200 SL in Pumpkin (fruiting veg.)

Intended use	Fruiting vegetable (according to the GAP BBCH ≥50)				
Active substance/product	acetamiprid				
Application rate (g/ha)	60				
Acute toxicity (mg/kg bw)	146				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	5.4	1	0.32	450.6
Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole Grass + cereals 100% grass	40.9		2.45	59.5
Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	5.2		0.31	46.9
~~Fruiting vegetables BBCH 10 – 49~~	~~Small herbivorous mammal "vole Grass + cereals 100% grass~~	~~136.4~~		~~8.18~~	~~17.8~~
~~Fruiting vegetables BBCH 10 – 49~~	~~Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods~~	~~17.2~~		~~1.03~~	~~141.5~~
Reprod. toxicity (mg/kg bw/d)	2.5				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	1.9	0.53	0.06	41.4
Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole Grass + cereals 100% grass	21.7		0.69	**3.6**
Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3		0.07	34.2

~~Fruiting vegetables BBCH 10 – 49~~	~~Small herbivorous mammal "vole Grass + cereals 100% grass~~	~~72.3~~		~~2.30~~	~~**1.1**~~
~~Fruiting vegetables BBCH 10 – 49~~	~~Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods~~	~~7.8~~		~~0.25~~	~~10.1~~

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-9: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of LEPTOSAR 200 SL in soybean (pulses)

Intended use	Pulses (soybean) BBCH 11-19 and 61-65
Active substance/product	acetamiprid
Application rate (g/ha)	60
Acute toxicity (mg/kg bw)	146
TER criterion	10

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Pulses BBCH ≥ 50	Large herbivorous mammal "lagomorph" Non-grass herbs 100% Non-grass herbs	10.5	1	0.63	231.7
Pulses BBCH ≥ 50	Small herbivorous mammal "vole Grass + cereals 100% grass	40.9	1	2.45	59.5
Pulses BBCH ≥ 50	Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	5.2	1	0.312	467.9
Pulses BBCH 10 – 19	Small insectivorous mammal "shrew" ground dwelling invertebrates without interception 100% ground arthropods	7.6	1	0.46	320.2
Pulses BBCH 10 - 49	Large herbivorous mammal "lagomorph" Non-grass herbs 100% Non-grass herbs	35.1	1	2.1	69.3
Pulses BBCH 10 - 49	Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	17.2	1	1.03	141.5

Reprod. toxicity (mg/kg bw/d)	2.5				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Pulses BBCH ≥ 50	Large herbivorous mammal "lagomorph" Non-grass herbs 100% Non-grass herbs	4.3	1 x 0.53	0.14	18.3
Pulses BBCH ≥ 50	Small herbivorous mammal "vole Grass + cereals 100% grass	21.7	1 x 0.53	0.69	**3.6**
Pulses BBCH ≥ 50	Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	1 x 0.53	0.07	34.2
Pulses BBCH 10 - 19	Small insectivorous mammal "shrew" ground dwelling invertebrates without interception 100% ground arthropods	4.2	1 x 0.53	0.13	18.7
Pulses BBCH 10 - 49	Large herbivorous mammal "lagomorph" Non-grass herbs 100% Non-grass herbs	14.3	1 x 0.53	0.19	5.5
Pulses BBCH 10 - 49	Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	1 x 0.53	0.25	10.1

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-10: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of LEPTOSAR 200 SL in tobacco (as maize)

Intended use	Tobacco (as maize)				
Active substance/product	acetamiprid				
Application rate (g/ha)	2 x 25				
Acute toxicity (mg/kg bw)	146				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Maize BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals All maize shoots + later grass	34.1	~~1.2~~	~~1.02~~	~~142.7~~
			1.4	1.19	122.7
Maize BBCH ≥ 40	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	4.3	~~1.2~~	~~0.13~~	~~1131.8~~
			1.4	0.15	973.3

Maize BBCH 30 - 39	Small herbivorous mammal "vole Grass + cereals All maize shoots + later grass	68.2	~~1.2~~	~~2.05~~	~~71,4~~
			1.4	2.39	61.1
Maize BBCH 30 - 39	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	8.6	~~1.2~~	~~0.26~~	~~565,9~~
			1.4	0.30	486.7
Maize BBCH≥20	Small insectivorous mamal "shrew"	5.4	1.4	0.19	768.4
Reprod. toxicity (mg/kg bw/d)	2.5				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals All maize shoots + later grass	18.1	~~1.4x0.53~~	~~0.34~~	~~7,4~~
			1.6 x 0.53	0.38	6.6
Maize BBCH ≥ 40	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	1.9	~~1.4x0.53~~	~~0.04~~	~~70,9~~
			1.6 x 0.53	0.04	62.5
Maize BBCH 30 - 39	Small herbivorous mammal "vole Grass + cereals All maize shoots + later grass	36.1	~~1.4x0.53~~	~~0.67~~	~~3,7~~
			1.6 x 0.53	0.77	**3.2**
Maize BBCH 30 - 39	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	3.9	~~1.4x0.53~~	~~0.07~~	~~34,6~~
			1.6 x 0.53	0.08	31.2
Maize BBCH≥20	Small insectivorous mamal "shrew"	1.9	1.6 x 0.53	0.04	62.5

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The risk assessment conducted at Tier 1 indicates an unacceptable acute risk to small herbivorous mammal vole exposed to LEPTOSAR 200 SL. It is concluded, therefore, that the use of LEPTOSAR 200 SL as proposed could be not safe for mammals in almost all of intended uses. A refined risk assessment is then required.

9.3.2.2 Higher-tier risk assessment

The first-tier TER values, calculated for recommended scenarios, did not exceed the relevant trigger values of 5 for long term risk assessment. Refined risk assessments were necessary. Acceptable risk to mammals was confirmed using the following refinements:

- Focal species,
- Deposition factor (DF) based on interception (IF) by crops dependent on growth stage
- **Proportions of feed item in the diet (PD) according to Rinke (1991)**

Selection of relevant focal species

The Guidance document (EFSA, 2009) proposes the common shrew (*Sorex araneus*), the common vole (*Microtus* arvalis) and the wood mouse (*Apodemus sylvaticus*) as representative focal species covering small insectivorous, herbivorous and omnivorous mammals, respectively, in maize according to the proposed GAP uses.
However generic field monitoring data (Wolf, 2005) on maize and beet fields of mammals and radio-tracking of wood mice in maize growing farmland area, are available. The study was conducted in spring on 5 maize and 5 sugar beet fields (and the surrounding habitat) in the "Tullnerfeld' region to the west of Vienna in Austria. To identity the mammal species that use plain fields, maize and sugar beet fields as part of their natural home range, live trapping of small mammals with mark-recapture was conducted. Additionally, radio telemetry was used to investigate the proportion of time spent in each habitat. The combination of these techniques gave information on relevant focal species and proportion of time they spent in the crops. Based on this data it was determined that vole and shrew were not species occurring regularly in maize and that Wood mouse is the relevant focal species for these exposure scenarios. Therefore, wood mouse should be considered as the focal species in the refined risk assessment for acetamiprid.

The relevance of the 'vole' scenarios for regulatory approvals of PPPs in crops is questionable because of the special biological characteristics of voles, particularly concerning population dynamics and resilience to stressors. Some of those key characteristics are: 1) Arable crops cannot be regarded as primary habitats for common voles; 2) Common vole populations naturally display cyclical changes, and a strong ability to recover from decimation due to their high reproductive potential; 3) Common voles are considered pests in many agricultural areas, since their high biomass consumption can lead to severe crop damage. Due to all uncertainties and discrepancies around the relevance of voles, the risk to small herbivorous mammals should be covered by the assessment of risk to another rodent, i.e. the omnivorous wood mouse (Apodemus sylvaticus).

Modern (i.e. commercial used) fruiting vegetables, vineyards, hops, most orchards and also nurseries and ornamentals are intensively managed crops particularly during the vole reproduction season in spring and summer. Besides the application of plant protection products, mechanical husbandry activities such as mowing, mulching and pruning, etc. take place. Mowing is a typical cultural practice in commercial vineyards, hops and orchards and is known to reduce the attractiveness for voles substantially (Pelz, 2002; Jaworska, 1995; Sulivan et al. 1987; Yletyinen & Norrdahl, 2008). Regular disturbances and low or absent vegetation cover (from mowing or herbicidal weeding) lead to vole population decline predominantly by increased exposure to predation from both diurnal and nocturnal predators. In conventional silage grassland, frequent mowing was followed by 'crashes' in common vole numbers (Jacob & Halle, 2001; Jacob & Hempel, 2003) which was largely due to an increased predation risk through birds of prey, owls, and mammalian predators. Likewise, Edge et al. (1995) found populations of grey-tailed voles (Microtus canicaudus) reduced by 50% after mowing. In addition, intensive irrigation (a common practice e.g. orchards in Southern countries) may flush out burrows of common voles, which are generally quite shallow with nest chambers located at an average depth of just 15 cm (Dieterlen, 2005) and runways located above-ground.

Furthermore, although voles are listed as relevant focal species, it is widely acknowledged that voles are not relevant for arable crops and orchards.

- Gurney, *et al.* (1998) reports the feeding habit of field voles (*Microusagrestis*) to be mainly rough, ungrazed grassland, including thick grass ground cover. In a two year study of small mammals on Scottish arable land and set-aside (Rodgers 19931) 159 field voles were caught, which were reported

to have an almost exclusive preference for rough grassland and were completely absent from the wood and also infrequent in set-aside and crops.
- In a three year study of small mammals on an arable farm in Oxfordshire Tew (19941) failed to capture any field voles away from hedgerows around cereal fields. In the Boxworth project, field voles were occasionally caught in the fields but this was restricted to areas with dense ground cover, such as patches infested with blackgrass (Johnson *et al*., 19921).
- No data are available from radio tracking studies for the bank vole or the field vole. Radio tracking has been tried unsuccessfully in both species (Plesner-Jensen 1993). Trapping studies have shown that although both species do not use arable fields as main habitat, they are common in hedgerows and woods adjacent to arable fields (Pollard &Relton 1970; Jefferies et al 1973; Green 1979; Loman 1991; Johnson et al. 1992).The preference of the common vole for non-cropped areas are discussed in Jacob *et al* (2014), in which it states: "The common vole is primarily a grassland species that is well adapted to steppe habitats. Primary habitats are meadows, set-aside land, flower strips, grassy field verges and alfalfa and clover fields. It prefers to inhabit undisturbed short vegetation and can be found in grass leys in forests after clear cuts and other grassy habitats."

Furthermore, information from DEFRA's research project on "Estimating wildlife exposure to pesticides in crops: additional scenarios and data" (2009) supports the non-relevance of the vole. The aim of this work was to provide further information on use of crops by wildlife by extensive surveying and by review of public literature. The following table taken from this report shows the number of captures of small mammals in the various habitat types.

Table 9.3-9: Captures of small mammals during 11,000 trap-events in different agricultural habitats (Table 3 from Report PS2328)

	Captures per 100 trap events						
	Potatoes	**Arable hedge**	**Cereal**	**Sugar beet**	**Other non-crop**	**Orchard hedge**	**Orchard crop**
Field vole	0	0.15	0.08	0	0	1.52	1.31
Pygmy shrew	0.02	0.53	0.23	0	0.34	1.82	0.51
Common shrew	0.38	6.43	1.36	1.00	6.38	3.33	1.85
Bank vole	0.02	6.43	1.44	0	1.55	4.24	0.27
Woodmouse	0.82	8.06	7.04	0.50	2.76	7.88	2.49
Total	1.24	21.6	10.15	1.5	11.03	18.79	6.43
Trap events in this habitat	5020	2630	2570	200	580	330	2970

Although the study did not specifically include all the intended crops, the results clearly show that wood mice are much more prevalent in arable crops (including potatoes, cereal and sugar beet) than voles. A follow on research project by DEFRA, on "Small mammal activity in soft fruit, cane fruit and top fruit orchards" (2012), focused only on the activity of wood mice as the key focal species. The report stated that "Although a number of species of small mammals occurred in orchards in PS2328 [DEFRA 2009], wood mice were caught in the greatest numbers and are probably at greatest risk from pesticides applied there. They are omnivorous and forage above ground, while shews and voles tend to forage beneath thatch and litter layers".

Additionally, in a study conducted in southern Moravia, Czech Republic, small mammal communities were snap trapped for six years in agricultural landscapes including vineyards (Heroldova et al., 2007) which is a comparable habitat to modern orchards. The dominant species in vineyards was also the wood mouse (*Apodemu ssylvaticus*), which comprised 93% of all small mammals trapped in this habitat. The

wood mouse was also regularly present in different types of vineyards in southwest Germany (Pedall et al., 2003). In contrast to the common vole, the wood mouse is a ubiquitous and euryoecious non-specialist (Tattersall et al., 1997), inhabiting a wide range of landscapes (Montgomery, 1999), and is found in arable habitats throughout the year (e.g. (Tew& Macdonald, 1994); (Loman, 1991); (Green, 1979); (Kikkawa, 1964); (Bergstedt, 1965)). This species has no specific habitat requirements, yet it tends to avoid habitats with a dense herb layer (Braun &Dieterlen, 2005). Tew et al. (2000) suggests that wood mice, due to their bouncing locomotion and granivorous habits, even favour habitats with partly bare ground over which they can easily travel and find fallen seed.

Taking all of the above into consideration (high fecundity and population recuperation of the vole; primary source of food outside crops fields for the vole; necessity of population control measures since the vole is considered a crop pest when high population levels are reached; other agricultural techniques being also means of population control), voles are not considered to be a relevant focal species. Therefore, the risk assessment for small herbivorous mammals can be concluded to be acceptable (even with TER lower than the trigger value) if it is acceptable for other small omnivorous mammals (wood mouse and brown hare) which are considered as a relevant focal species.

Due to all uncertainties and discrepancies around the relevance of voles, the risk to small herbivorous mammals should be covered by the assessment of risk to another rodent, i.e. the omnivorous wood mouse (Apodemus sylvaticus).

Review Comments:

The voles are relevant species for Poland. Thus, further assessment is required.

Taking this considerations into account, the calculated TERs show that there is no unacceptable acute and long-term risk for wood mouse from application of LEPTOSAR 200SL in all intended uses.

- Oilseed rape – Refined risk assessment following Deposition factor (DF) based on interception (IF) by crops dependent on growth stage

Shortcut values for mean RUDs included in Table I.1, Annex I of EFSA Guideline for most of crop scenarios are calculated considering that whole sprayed plant protection product is deposited on food items. However, in more realistic scenario at certain stages the crop intercepts itself less than full application rate and therefore, concentration on this food item is respectively lower.
Shortcut value for mean RUD included in Table I.2, Annex I of EFSA Guideline for crop scenario "Oilseed rape BBCH ≥ 40" equal 18.1 was calculated considering that the 25 % plant protection product is deposited on food item.
Based on FOCUS Ground Water Assessments (May 2014) Interception Factor for oilseed rape at BBCH stage from 40-89 is equal 0.8. Thus, for food item value of 0.2 (DF) was used in calculations.

Table 9.3-10: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of LEPTOSAR 200 SL in oilseed rape – refined parameters (*) are further described and justified in the text

Intended use	**Oilseed rape** (also: *Flax, common hemp, opium poppy*)						
Active substance/product	acetamiprid						
Application rate (g/ha)	60						
Reprod. toxicity (mg/kg bw/d)	2.5						
TER criterion	5						
Focal species	**Food category. % in diet**	**FIR/bw**	**RUD_m × DF (mg/kg food)**	**MAF_m × TWA**	**PT**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
common vole (*Microtus* arvalis	100% grass	1.33	10.84 (54.2 x 0.2)	0.53	1	0.46	5.43
	Whole diet					0.46	5.43

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

- Soybean – Refined risk assessment following Deposition factor (DF) based on interception (IF) by crops dependent on growth stage

Shortcut values for mean RUDs included in Table I.1, Annex I of EFSA Guideline for most of crop scenarios are calculated considering that whole sprayed plant protection product is deposited on food items. However, in more realistic scenario at certain stages the crop intercepts itself less than full application rate and therefore, concentration on this food item is respectively lower.
Shortcut value for mean RUD included in Table I.2, Annex I of EFSA Guideline for crop scenario "Pulses ≥ 50" equal 21.7 was calculated considering that the 30 % plant protection product is deposited on food item.
However, based on FOCUS Ground Water Assessments (May 2014) Interception Factor for soybean at BBCH stage from 40-89 is equal 0.85. Thus, for food item value of 0.15 (DF) was used in calculations.

Table 9.3-11: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of LEPTOSAR 200 SL in soybean – refined parameters (*) are further described and justified in the text

Intended use	**Soybean (Pulses)**						
Active substance/product	acetamiprid						
Application rate (g/ha)	60						
Reprod. toxicity (mg/kg bw/d)	2.5						
TER criterion	5						
Focal species	**Food category. % in diet**	**FIR/bw**	**RUD_m × DF (mg/kg food)**	**MAF_m × TWA**	**PT**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
common vole (*Microtus* arvalis	100% grass	1.33	8.13 (54.2 x 0.15)	0.53	1	0.34	7.35
	Whole diet					0.34	7.35

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-12: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of LEPTOSAR 200 SL in pumpkin (at BBCH >50) – refined parameters (*) are further described and justified in the text

Intended use	Pumpkin
Active substance/product	acetamiprid
Application rate (g/ha)	60
Reprod. toxicity (mg/kg bw/d)	2.5
TER criterion	5

Focal species	**Food category. % in diet**	**FIR/bw**	**RUD_m × DF (mg/kg food)**	**MAF_m × TWA**	**PT**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
common vole (*Microtus* arvalis	100% grass	1.33	8.13 (54.2 x 0.15)	0.53	1	0.34	7.35
	Whole diet					0.34	7.35

*DF value of 0.15 based on FOCUS Ground Water Assessments (May 2014) Interception Factor for potatoes

Proportions of feed item in the diet (PD) according to Rinke (1991)

Studies by Rinke[2] and Lüthi et all[2] are commonly used for purposes of the refinement of the risk at National and Zonal level.

In the study by Rinke were investigates vole feeding preferences (mono versus dicot) via stomach content analysis. No exact percentages of each per animal were determined, instead, animals were categorized into 5 potential categories of dicot consumption (20% intervals). Overall, despite the fact that more monocots were available in the surrounding areas (70%), voles showed a preference for dicots, with the majority of voles (all seasons, sexes, ages) showing >80% dicot material in stomach contents.

~~Additionally, in Lüthi et all[3] also an extensive study on the diet of the common vole in monocot and dicot dominated fields was performed. The study is very detailed (considering that it is public literature) and a large number of samples/voles were considered.~~

As stated above, for the representative small herbivore as relevant for Tier 1 assessments, the vole conservatively is assumed solely to feed on grasses, the feed item reported to contain the highest residue levels (default mean RUD = 54.2 mg/kg) together with the lowest assimilation efficiency and low food energy.

Studies have demonstrated that common voles (*Microtus arvalis*) prefer to consume dicotyledons rather than monocotyledonous grasses. A study of the diet of the common vole in grassland in Germany examined the diet of 363 individuals caught by snap-trapping through analysis of stomach contents (Rinke (1990[1]; 1991[2]). The results showed that dicotyledons, such as Taraxacum officinale and Trifolium pratense, were preferred and were eaten at a higher frequency than would be expected from their relative occurrence in the grassland habitat in question. Therefore, the risk assessment can be refined by considering a common vole consuming a diet comprising 50% dicotyledons (non-grass herbs) and 50% grasses.

[2] Rinke, T. 1990. Zur Nahrungsökologie von Microtus arvalis (Pallas, 1778) auf Dauergrünland. I. Allgemeine Nahrungspräferenzen. Zeitschrift für Säugetierkunde 55: 106-114

[3] Rinke, T. (1991). Percentage of volume versus number of species: availability and intake of grasses and forbs in Microtus arvalis. Folia Zoologica 40 (2): 143 – 151.

FIRtotal,fresh											
Food category	**PD (% diety)**	**FE (kJ/ dry g)**	**MC (%)`**	**AE (%)**	**FE (kJ/g fresh)**	**DEE (kJ)**	**FEtotal,fresh**	**Daily intake rate (g fresh weight/d)**	**FIRtotal,fresh**	**FIR/bw**	**FIRtotal/bw**
Monocotyledonous plants	50	17,6	76,4	47	0,976096	-	1,78	18,27	36,55	0,731	1,46
Dicotyledonous plants	50	17,8	88,1	76	0,804916	-		18,27		0,731	
Total	-	-	-	-	1,781012	65,09		-			-

Review Comments:

The zRMS-PL agree with proposal of refined PD value for voles and the FIR/bw value calculation. This assumption is supported in the RAR (2016). Overall it is concluded in the RAR that "*the study cannot be used to determine a quantitative PD (mono versus dicotyledonous plant matter), however, it can be used to determine that the actual diet of the common vole typically contains both monocotyledons and dicotyledons and that dicots will comprise >50% of the diet under normal circumstances.*" Therefore, the following risk assessment assumes a diet of 50% monocots and 50% dicots (i.e. PD of 0.5 monocots and 0.5 dicots) in line with the EU review.

Table 9.3-12: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of LEPTOSAR 200 SL in maize – refined parameters (*) are further described and justified in the text

Crop grouping / growth stage	Food type	RUD a (mg a.s./kg)	DF*	App. rate (kg a.s./ha)	FIR/bw	MAF	fTWA	PT	Refined DDD (mg a.s/kg bw/day)	TER LT
mono	Grasses (0.5)	54.2	0.25	0.060	1.46	1	0.53	1	0.31	
dic	Nongrass herbs (0.5)	28.7	0.25			1	0.53	1	0.16	
TOTAL									0.47	5.3

*DF value of 0.25 for maize at BBCH >40 (Efsa 2009)

Table 9.3-13: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of LEPTOSAR 200 SL in tobacco (as maize BBCH 30-39)– refined parameters (*) are further described and justified in the text

~~Crop grouping / growth stage~~	~~Food type~~	~~RUD a (mg a.s./kg)~~	~~DF*~~	~~App. rate (kg a.s./ha)~~	~~FIR/bw~~	~~MAF (14 d)~~	~~fTWA~~	~~PT~~	~~Refined DDD (mg a.s/kg bw/day)~~	~~TER LT~~
~~mono~~	~~Grasses (0.5)~~	~~54.2~~	~~0.3~~	~~0.025~~	~~1.46~~	~~1.4~~	~~0.53~~	~~1~~	~~0.22~~	

dic	Nongrass herbs (0.5)	28.7	0.3			1.4	0.53	1	0.12	
TOTAL									0.34	7.4

*DF value of 0.3 based on FOCUS Ground Water Assessments (May 2014) Interception Factor for tobacco at BBCH 20- 39 (Efsa 2009)

Food type	PD	RUD (mg a.s./kg)	DF*	App. rate (kg a.s./ha)	FIR/bw	MAF	fTWA	Refined DDD (mg a.s/kg bw/day)	TER LT
2 x 25 g a.s./ha with 7 d interval									
Grasses	0.5	54.2	0.5	0.025	1.46	1.6	0.53	0.42	
Non-grass herbs	0.5	28.7						0.22	
TOTAL								0.64	**3.9**
1 x 25 g a.s./ha									
Grasses	0.5	54.2	0.5	0.025	1.46	1	0.53	0.26	
Non-grass herbs	0.5	28.7						0.14	
TOTAL								0.40	6.25

*DF value of 0.5 for maize at BBCH 30-39 (EFSA 2009)

Table 9.3-14: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of LEPTOSAR 200 SL in ornamental and nursery – refined parameters (*) are further described and justified in the text

Crop grouping / growth stage	Food type	RUD a (mg a.s./kg)	DF*	App. rate (kg a.s./ha)	FIR/bw	MAF	fTWA	PT	Refined DDD (mg a.s/kg bw/day)	TER LT
mono	Grasses (0.5)	54.2	0.4	0.040		1	0.53	1	0.33	
dic	Nongrass herbs (0.5)	28.7	0.4		1.46	1	0.53	1	0.17	
TOTAL									0.5	5.0

*DF value of 0.4 based on FOCUS Ground Water Assessments (May 2014) Interception Factor for vines at BBCH 10- 69 (Efsa 2009)

Table 9.3-15: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of LEPTOSAR 200 SL in pumpkin (at BBCH >50) – refined parameters (*) are further described and justified in the text

Crop grouping / growth stage	Food type	RUD a (mg a.s./kg)	DF*	App. rate (kg a.s./ha)	FIR/bw	MAF	fTWA	PT	Refined DDD (mg a.s/kg bw/day)	TER LT
mono	Grasses (0.5)	54.2	0.15	0.060		1	0.53	1	0.19	
dic	Nongrass herbs (0.5)	28.7	0.15		1.46	1	0.53	1	0.10	
TOTAL									0.29	8.6

*DF value of 0.15 based on FOCUS Ground Water Assessments (May 2014) Interception Factor for potatoes at BBCH 51- 89 (Efsa 2009)

9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

To achieve a concise risk assessment. the risk envelope approach is applied. Here. the assessment for the use in maize also covers the risk for mammals from all other intended uses (see 9.1.8).

With a K(f)oc of 100.2 (geometric mean), acetamiprid belongs to the group of less sorptive substances

Effective application rate (g/ha)	=	60		
Acute toxicity (mg/kg bw)	=	146	quotient	= 0.41
Reprod. toxicity (mg/kg bw/d)	=	2.5	quotient	= 24

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of acetamiprid amounts to 0.80 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating mammals via secondary poisoning

Not required.

Risk assessment for fish-eating mammals via secondary poisoning

Not required.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.4 Overall conclusions.

There is no potential risk for mammals resulting from acute exposure or long-term exposure to active substance following use of LEPTOSAR 200 SL in compliance with GAP.

Review Comments:

The acute and chronic risks of LEPTOSAR 200 SL to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from study with active ingredient, and maximum and the refined residues occurring on food items. No additional assessment for formulation was required.

All TER values exceed the relevant triggers indicating that LEPTOSAR 200 SL does not pose an unacceptable risk to mammals following applications according to recommended and accepted use pattern (for tobacco at BBCH 30-39 only one application is allowed).

Evaluation of exposing to mammals through the drinking water demonstrated the acceptable risk. The risk to earthworm- and fish-eating animals from secondary poisoning is not required.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

No data/information available.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with acetamiprid and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of LEPTOSAR 200 SL were not evaluated as part of the EU assessment of acetamiprid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – acetamiprid and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Fish				
Oncorhynchus mykiss	acetamiprid	96 h, s	LC_{50} > 100 mg a.s./L (nom)	EFSA, 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610, 91 pp. doi:10.2903/j.efsa.2016.4610
Lepomis macrochiru	acetamiprid	96 h, f	LC_{50} > 119.3 mg a.s./L (mm)	
Cyp rinodon variegatus	acetamiprid	96 h, f	LC_{50} = 100 mg a.s./L (nom)	
Pimephales promelas	acetamiprid	35 d, f	NOEC = 9.4 g a.s./L (mm)	
Oncorhynchus mykiss	Metabolite IM-1-4	96 h, ss	LC_{50} > 98.1 mg p.m./L (mm)	
Amphibians				
Xenopis laevis	acetamiprid	21 d, f	2.6 mg a.s./L(mm)	EFSA, 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610, 91 pp. doi:10.2903/j.efsa.2016.4610
Aquatic invertebrates				
Daphnia magna	acetamiprid	48 h, s	EC_{50} = 49.8 mg a.s./L mm	EFSA, 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610, 91 pp. doi:10.2903/j.efsa.2016.4610
Chironomus riparius	acetamiprid	48 h, s	EC_{50} = 0.0207 mg a.s./L mm	
Gammarus fasciatu	acetamiprid	96 h, s	EC_{50} = 0.1 mg a.s./L mm	
Mysidopsis bahi	acetamiprid	96 h, f	EC_{50} = 0.066 mg a.s./L mm	
Gammarus pulex	acetamiprid	96 h, s	EC_{50} = 0.050 mg a.s./L mm	
Simulium latigonium	acetamiprid	96 h, s	EC_{50} = 0.0037 mg a.s./L mm	
Geometric mean aquatic insects	acetamiprid	-	**EC_{50} = 0.0085 mg a.s./L mm**	
Daphnia magna	acetamiprid	21 d, ss	NOEC = 5 mg a.s./L mm EC_{10} = 2.96 mg a.s./L mm	
Daphnia magna	Metabolite IM-1-2	48 h, ss	LC_{50} > 99.8 mg pm/L	
Chironomus riparius	Metabolite IM-1-2	48 h, s	LC_{50} = 15.0 mg pm/L	
Daphnia magna	Metabolite IM-1-4	48 h, ss	LC_{50} = 43.9 mg pm/L	
Mysidopsis bahia	Metabolite IM-1-4	48 h, s	LC_{50} = 19 mg pm/L	
Chironomus riparius	Metabolite IM-1-4	48 h, s	LC_{50} = 76 mg pm/L	

Species	Substance	Exposure System	Results	Reference
Daphnia magna	Metabolite IM-1-5	48 h, s	LC_{50} = 25 mg pm/L	
Chironomus riparius	Metabolite IM-1-5	48 h, s	LC_{50} = 68 mg pm/L	
Daphnia magn	Metabolite IM-1-5	21 d, ss	LC_{50} = 26 mg pm/L	
Daphnia magna	Metabolite IC-0	48 h, ss	LC_{50} > 95.1 mg pm/L	
Chironomus riparius	Metabolite IC-0	48 h, s	LC_{50} > 100 mg pm/L	
Daphnia magna	Metabolite IB-1-1	48 h, ss	LC_{50} > 100.8 mg pm/L	
Chironomus riparius	Metabolite IB-1-1	48 h, s	LC_{50} > 100 mg pm/L	
Sediment-dwelling organisms				
Chironomus riparius	acetamiprid	28 d, s	NOEC = 0.00096 mg a.s./L $_{mm}$ EC_{10} = **0.000235** mg a.s./L $_{mm}$	EFSA, 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610, 91 pp. doi:10.2903/j.efsa.2016.4610
Algae				
Scenedesmus subspicatus	acetamiprid	72 h, s	E_rC_{50}; E_bC_{50} > 98.3 mg a.s./L $_{mm}$	EFSA, 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610, 91 pp. doi:10.2903/j.efsa.2016.4610
Anabaena flos - aquae	acetamiprid	120 h, s	EC_{50} >1.3 mg a.s./L $_{mm}$	
Higher plant				
Lemna gibba	acetamiprid	14 d, s	EC_{50} > 1.0 mg a.s./L $_{mm}$	EFSA, 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610, 91 pp. doi:10.2903/j.efsa.2016.4610
~~**Higher-tier studies (micro- or mesocosm studies)**~~				
~~Outdoor mesocosm study: Effect assessment on macroinvertebrates, zooplankton, phytoplankton, periphyton and macrophytes in outdoor mesocosms. Test substance: Acetamiprid 20 SG (Mospilan 20 SG). 2 applications with a 14 day interval. Study duration: 82 days. Treatment rates: 0.5, 1.1, 2.6 and 6.0 µg a.s./L. Endpoints: NOEC and NOEAEC <0.5 µg/L based on class 5B effects on Naididae at 0.5–6.0 µg/L . Considering however the uncertainty associated with the findings for Naididae (not expected to be more sensitive than insects based on mode of action; relatively low numbers in control, although MDD was low) the reported conclusion by the study author NOEC based on class 2 effects to derive the ETO RAC 1.1 µg/L; NOEAEC to derive ERO RAC 1.1 µg/L based on class 5B effects on Cloeon dipterum at 2.6 µg/L) could be acceptable in case the findings for Naididae in the present study are negated by prolonged toxicity laboratory studies (e.g. at least 28 days duration) with representative taxa of Naididae. Potential endocrine disrupting properties (Annex Part A, point 8.2.3) The mammalian toxicology data was considered, along with the amphibian metamorphosis assay and the fish early life stage test. These data do not indicate an endocrine system specific pathway of toxicity (i.e. systemic toxicity is indicated, as opposed to direct interaction with estrogen, androgen or thyroidal systems).~~				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – LEPTOSAR 200 SL

Species	Substance	Exposure System	Results	Reference
Daphnia magna	formulation	48 h, s	EC_{50} > 100 mg/L $_{nom}$	Elżbieta Kulec-Płoszczyca, 2019, W/01/19
Daphnia magna	formulation	21d, ss	EC_{50} > 10 mg/L $_{nom}$	Katarzyna Brzozowska-Wojoczek, 2019, W/04/19
Pseudokirchneriella subcapitata	formulation	72 h, s	E_rC_{50} > 100mg /L $_{nom}$ E_yC_{50} > 100 mg/L $_{nom}$	Elżbieta Kulec-Płoszczyca, 2019, W/03/19
Chironomus sp.	formulation	48 h, s	EC_{50} = 0.0104 mg/L $_{nom}$	Paweł Bąk, 2019, W/02/19

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

9.5.1.1 Justification for new endpoints

No deviation from EU agreed endpoints.

Review Comments:

The lowest acute endpoint for invertebrates is 3.7 µg a.s./L. Thus, the RAC_{lowest} is 0.0617 µg a.s./L (EP/AF 60) and should be considered in the risk assessment as a "safety net" to the $RAC_{geomean}$. Nevertheless, as the overall RAC value is derived based on chronic endpoint for *Ch. riparius*, in zRMS opinion, additional calculations are not required (no impact on the RA conclusion). Therefore, there is no deviation from EU agreed endpoints.

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).
The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.

Review Comments:

Five potentially relevant surface water metabolites have been identified for consideration in the aquatic risk assessment: IM-1-2, IM-1-4, IC-0, IM-1-5 and IB-1-1. The toxicity of all metabolites is considerably lower than the toxicity of the active substance. Therefore, the risk from exposure to the metabolites is covered by the risk assessment for the active substance and a specific risk assessment for the metabolites is not considered necessary.

In the following table, the ratios between predicted environmental concentrations in surface water bodies (PEC_{SW}, PEC_{SED}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for acetamiprid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of LEPTOSAR 200 SL in all intended uses according to the GAP

Group		**Fish acute**	**Fish prolonged**	**Inverte b. acute**	**Inverteb. prolonge d**	**Algae**	**Highe r plant**	**Sed. dwell. prolonged**	**Amphibia ns**
Test species		***Oncorhynch us variegatus***	***Pimephal es promelas***	***Geomea n of EC50 of 2 aquatic insect species* ****	***Daphnia magna***	***Anabaen a flos - aquae***	***Lemn a gibba***	***Chironom us riparius***	
Endpoint (µg/L)		LC_{50} 100000	NOEC 9400	EC_{50} 8.5 µg/L	NOEC 2960 µg/L	EC_{50} >1300 µg/L	EC_{50} >1000 µg/L	NOEC 0.235 µg/L	NOEC 2600 µg/L
AF		100	10	100	10	10	10	10	10
RAC (µg/L)		1000	940	0.085	296	>130	>100	0.0235	260
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**								
Maize									
Step 1									
	18.1554	0.02	0.02	**213.59**	0.06	0.14	0.18	**772.57**	0.07
Step 2									
N-Europe	0.5866	-	-	**6.9**	-	-	-	**24.96**	-
Step 3									
D3/ditch	0.3145	-	-	**3.7**	-	-	-	**13.38**	-
D4/pond	0.01271	-	-	0.15	-	-	-	0.54	-
D4/stream	0.2817	-	-	**3.31**	-	-	-	**11.99**	-
R1/pond	0.03394	-	-	0.40	-	-	-	**1.44**	-
R1/stream	0.5513	-	-	**6.49**	-	-	-	**23.46**	-
Winter Cereals									
Step 1									
	12.1036	0.01	0.01	**142.40**	0.04	0.09	0.12	**515.05**	0.05
Step 2									
N-Europe	0.4084	-	-	**4.80**	-	-	-	**17.38**	-
Step 3									
D3/ditch	0.2537	-	-	**2.98**	-	-	-	**10.80**	-

Group		**Fish acute**	**Fish prolonged**	**Inverte b. acute**	**Inverteb. prolonge d**	**Algae**	**Highe r plant**	**Sed. dwell. prolonged**	**Amphibia ns**
Test species		***Oncorhynch us variegatus***	***Pimephal es promelas***	***Geomea n of EC50 of 2 aquatic insect species* ****	***Daphnia magna***	***Anabaen a flos - aquae***	***Lemn a gibba***	***Chironom us riparius***	
Endpoint (µg/L)		LC_{50} 100000	NOEC 9400	EC_{50} 8.5 µg/L	NOEC 2960 µg/L	EC_{50} >1300 µg/L	EC_{50} >1000 µg/L	NOEC 0.235 µg/L	NOEC 2600 µg/L
AF		100	10	100	10	10	10	10	10
RAC (µg/L)		1000	940	0.085	296	>130	>100	0.0235	260
D4/pond	0.008746	-	-	0.10	-	-	-	0.37	-
D4/stream	0.1993	-	-	**2.34**	-	-	-	**8.48**	-
R1/pond	0.03650	-	-	0.43	-	-	-	**1.55**	-
R1/stream	0.5768	-	-	**6.79**	-	-	-	**24.54**	-
Spring Cereals									
Step 1									
	12.1036	0.0	0.01	**142.40**	0.04	0.09	0.12	**515.05**	0.05
Step 2									
N-Europe	0.6512	-	-	**7.66**	-	-	-	**27.71**	-
Step 3									
D3/ditch	0.2537	-	-	**2.98**	-	-	-	**10.80**	-
D4/pond	0.008747	-	-	0.10	-	-	-	0.37	-
D4/stream	0.2073	-	-	**2.44**	-	-	-	**8.82**	-
Winter Oilseed Rape									
Step 2									
N-Europe	0.6126	-	-	**7.21**	-	-	-	**26.07**	-
Step 3									
D3/ditch	0.3793	-	-	**4.46**	-	-	-	**16.14**	-
D4/pond	0.01311	-	-	0.15	-	-	-	0.56	-
D4/stream	0.2837	-	-	**3.34**	-	-	-	**12.07**	-
R1/pond	0.01312	-	-	0.15	-	-	-	0.56	-
R1/stream	0.2500	-	-	**2.94**	-	-	-	**10.64**	-
Spring Oilseed rape									
Step 1									

Group		**Fish acute**	**Fish prolonged**	**Inverte b. acute**	**Inverteb. prolonge d**	**Algae**	**Highe r plant**	**Sed. dwell. prolonged**	**Amphibia ns**
Test species		***Oncorhynch us variegatus***	***Pimephal es promelas***	***Geomea n of EC50 of 2 aquatic insect species* ****	***Daphnia magna***	***Anabaen a flos - aquae***	***Lemn a gibba***	***Chironom us riparius***	
Endpoint (µg/L)		LC_{50} 100000	NOEC 9400	EC_{50} 8.5 µg/L	NOEC 2960 µg/L	EC_{50} >1300 µg/L	EC_{50} >1000 µg/L	NOEC 0.235 µg/L	NOEC 2600 µg/L
AF		100	10	100	10	10	10	10	10
RAC (µg/L)		1000	940	0.085	296	>130	>100	0.0235	260
	18.1554	0.02	0.02	**213.59**	0.06	0.14	0.18	**772.57**	0.07
Step 2									
N-Europe	0.7687	-	-	**9.04**	-	-	-	**32.71**	-
Step 3									
D3/ditch	0.3804	-	-	**4.47**	-	-	-	**16.17**	-
D4/pond	0.01312	-	-	0.14	-	-	-	0.56	-
D4/stream	0.3116	-	-	**3.67**	-	-	-	**13.26**	-
R1/pond	0.01312	-	-	0.15	-	-	-	0.56	-
R1/stream	0.2504	-	-	**2.95**	-	-	-	**10.66**	-
Pome fruits (2 x 25g as/ha) ~~BBCH 11~~									
Step 1									
	19.5358	0.02	0.02	**831.3**	0.07	0.15	0.20	**831.31**	0.08
Step 2									
N-Europe	3.7573	-	-	**44.20**	-	-	-	**159.89**	-
~~Step 3~~									
~~D3/ditch~~	~~1.671~~	-	-	~~**19.66**~~	-	-	-	~~**19.66**~~	-
~~D4/pond~~	~~0.1587~~	-	-	~~**1.87**~~	-	-	-	~~**6.75**~~	-
~~D4/stream~~	~~1.690~~	-	-	~~**19.88**~~	-	-	-	~~**71.91**~~	-
~~R1/pond~~	~~0.1910~~	-	-	~~**2.25**~~	-	-	-	~~**8.13**~~	-
~~R1/stream~~	~~1.340~~	-	-	~~**15.76**~~				~~**57.02**~~	-
Pome fruits (2 x 25g as/ha), BBCH 51									
D3/ditch	1.678	-	-	**19.74**	-	-	-	**71.40**	-
D4/pond	0.1517	-	-	**1.85**	-	-	-	**6.46**	-
D4/stream	1.762	-	-	**20.73**	-	-	-	**74.98**	-
R1/pond	0.1772	-	-	**2.08**	-	-	-	**7.54**	-
R1/stream	1.348	-	-	**15.86**	-	-	-	**57.36**	-

Group		**Fish acute**	**Fish prolonged**	**Inverte b. acute**	**Inverteb. prolonge d**	**Algae**	**Highe r plant**	**Sed. dwell. prolonged**	**Amphibia ns**
Test species		***Oncorhynch us variegatus***	***Pimephal es promelas***	***Geomea n of EC50 of 2 aquatic insect species* ****	***Daphnia magna***	***Anabaen a flos - aquae***	***Lemn a gibba***	***Chironom us riparius***	
Endpoint (µg/L)		LC_{50} 100000	NOEC 9400	EC_{50} 8.5 µg/L	NOEC 2960 µg/L	EC_{50} >1300 µg/L	EC_{50} >1000 µg/L	NOEC 0.235 µg/L	NOEC 2600 µg/L
AF		100	10	100	10	10	10	10	10
RAC (µg/L)		1000	940	0.085	296	>130	>100	0.0235	260
~~Pome fruits, 50g as/ha (*Ornamentals*)~~									
~~Step 1~~									
	~~19.5358~~	~~0.02~~	~~0.02~~	~~**831.3**~~	~~0.07~~	~~0.15~~	~~0.20~~	~~**831.31**~~	~~0.08~~
~~Step 2~~									
~~N Europe~~	~~4.8662~~	~~-~~	~~-~~	~~**57.25**~~	~~-~~	~~-~~	~~-~~	~~**207.07**~~	~~-~~
~~Step 3~~									
~~D3/ditch~~	~~3.883~~	~~-~~	~~-~~	~~**45.68**~~	~~-~~	~~-~~	~~-~~	~~**165.34**~~	~~-~~
~~D4/pond~~	~~0.2360~~	~~-~~	~~-~~	~~**2.78**~~	~~-~~	~~-~~	~~-~~	~~**10.04**~~	~~-~~
~~D4/stream~~	~~3.741~~	~~-~~	~~-~~	~~**44.01**~~	~~-~~	~~-~~	~~-~~	~~**159.19**~~	~~-~~
~~R1/pond~~	~~0.2360~~	~~-~~	~~-~~	~~**2.78**~~	~~-~~	~~-~~	~~-~~	~~**10.04**~~	~~-~~
~~R1/stream~~	~~3.140~~	~~-~~	~~-~~	~~**36.94**~~	~~-~~	~~-~~	~~-~~	~~**133.62**~~	~~-~~
Pome fruits, 40g as/ha (*Ornamentals*)									
D3/ditch	3.106	-	-	**36.54**	-	-	-	**132.17**	-
D4/pond	0.1888	-	-	**2.22**	-	-	-	**8.03**	-
D4/stream	2.993	-	-	**35.21**	-	-	-	**127.36**	-
R1/pond	0.1888	-	-	**2.22**	-	-	-	**8.03**	-
R1/stream	2.512	-	-	**29.55**	-	-	-	**106.89**	-
~~Pumpkin (potatoes)~~									
~~Step 1~~									
	~~18.1554~~	~~0.02~~	~~0.02~~	~~**213.59**~~	~~0.06~~	~~0.14~~	~~0.18~~	~~**772.57**~~	~~0.07~~
~~Step 2~~									
~~N Europe~~	~~0.7166~~	~~-~~	~~-~~	~~**8.43**~~	~~-~~	~~-~~	~~-~~	~~**30.49**~~	~~-~~
~~Step 3~~									
~~D3/ditch~~	~~0.3145~~	~~-~~	~~-~~	~~**3.70**~~	~~-~~	~~-~~	~~-~~	~~**13.38**~~	~~-~~

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher plant**	**Sed. dwell. prolonged**	**Amphibians**
Test species		***Oncorhynchus variegatus***	***Pimephales promelas***	***Geomean of EC50 of 2 aquatic insect species******	***Daphnia magna***	***Anabaena flos - aquae***	***Lemna gibba***	***Chironomus riparius***	
Endpoint (µg/L)		LC_{50} 100000	NOEC 9400	EC_{50} 8.5 µg/L	NOEC 2960 µg/L	EC_{50} >1300 µg/L	EC_{50} >1000 µg/L	NOEC 0.235 µg/L	NOEC 2600 µg/L
AF		100	10	100	10	10	10	10	10
RAC (µg/L)		1000	940	0.085	296	>130	>100	0.0235	260
~~D4/pond~~	~~0.01270~~	-	-	~~0.32~~	-	-	-	~~0.54~~	-
~~D4/stream~~	~~0.2456~~	-	-	~~**2.89**~~	-	-	-	~~**10.45**~~	-
~~R1/pond~~	~~0.04120~~	-	-	~~0.48~~	-	-	-	~~**1.75**~~	-
~~R1/stream~~	~~0.4842~~	-	-	~~**5.97**~~	-	-	-	~~**20.60**~~	-
Pumpkin (potatoes), 60g a.s./ha, BBCH >50									
Step 1									
	18.1554	0.02	0.02	**213.59**	0.06	0.14	0.18	**772.57**	0.07
Step 2									
N-Europe	0.7166	-	-	**8.43**	-	-	-	**30.49**	-
Step 3									
D3/ditch	0.3146	-	-	**3.7**	-	-	-	**13.39**	-
D4/pond	0.0127	-	-	0.14	-	-	-	0.54	-
D4/stream	0.2365	-	-	**2.78**	-	-	-	**10.06**	-
R1/pond	0.0681	-	-	0.80	-	-	-	**2.90**	-
R1/stream	0.7731	-	-	**9.10**	-	-	-	**32.90**	-
Opium poppy (as S OSR), 30g a.s./ha, BBCH 10									
Step 1									
	9.0777	0.01	0.01	**106.8**	0.03	0.07	0.09	**386.3**	0.035
Step 2									
N-Europe	0.3843	-	-	**4.52**	-	-	-	**16.35**	-
Step 3									
D3/ditch	0.1900	-	-	**2.24**	-	-	-	**8.09**	-
D4/pond	0.0066	-	-	0.08	-	-	-	0.28	-

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher plant**	**Sed. dwell. prolonged**	**Amphibians**
Test species		***Oncorhynchus variegatus***	***Pimephales promelas***	***Geomean of EC50 of 2 aquatic insect species******	***Daphnia magna***	***Anabaena flos - aquae***	***Lemna gibba***	***Chironomus riparius***	
Endpoint (µg/L)		LC_{50} 100000	NOEC 9400	EC_{50} 8.5 µg/L	NOEC 2960 µg/L	EC_{50} >1300 µg/L	EC_{50} >1000 µg/L	NOEC 0.235 µg/L	NOEC 2600 µg/L
AF		100	10	100	10	10	10	10	10
RAC (µg/L)		1000	940	0.085	296	>130	>100	0.0235	260
D4/stream	0.1558	-	-	**1.83**	-	-	-	**6.63**	-
R1/pond	0.0066	-	-	0.08	-	-	-	0.28	-
R1/stream	0.1252	-	-	**1.47**	-	-	-	**5.33**	-
Soybean (as legumes), 60g a.s./ha, BBCH 11									
Step 1									
	18.1554	0.02	0.02	**213.59**	0.06	0.14	0.18	**772.57**	0.07
Step 2									
N-Europe	0.8727	-	-	**10.27**	-	-	-	**37.14**	-
Step 3									
D3/ditch	0.3144	-	-	**3.70**	-	-	-	**13.38**	-
D4/pond	0.0127	-	-	0.15	-	-	-	0.54	-
D4/stream	0.2559	-	-	**3.01**	-	-	-	**10.89**	-
R1/pond	0.0127	-	-	0.15	-	-	-	0.54	-
R1/stream	0.2175	-	-	**2.56**	-	-	-	**9.26**	-
Sunflower (as maize), 50g a.s./ha, BBCH 10									
Step 1									
	15.1295	0.02	0.02	**177.99**	0.06	0.12	0.15	**643.81**	0.06
Step 2									
N-Europe	0.7273	-	-	**8.56**	-	-	-	**30.95**	-
Step 3									
D3/ditch	0.2623	-	-	**3.09**	-	-	-	**11.16**	-
D4/pond	0.0106	-	-	0.12	-	-	-	0.45	-
D4/stream	0.2246	-	-	**2.64**	-	-	-	**9.56**	-
R1/pond	0.0139	-	-	0.16	-	-	-	0.59	-
R1/stream	0.2475	-	-	**2.91**	-	-	-	**10.53**	-

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC

ratios above the relevant trigger of 1 are shown in bold

For all intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms. The trigger values were not achieved in case of aquatic invertebrates (acute) and sediment dwelling organisms (prolonged) in mostly FOCUS Steps 1-3 scenarios. Therefore, further assessment is necessary / further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

At Step 4 drift mitigation of the pesticide was calculated for different buffer zones with connection of run-off mitigation via vegetated filter strip efficiency using the VFSmod model. Additionally, the run-off reduction was consideredt with a vegetative buffer of 18-20 m (by reducing mass of pesticide in aqueous phase by 80% and mass of eroded sediment by 95%)

Table 9.5-5: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data with mitigation of spray drift and run-off for the use of LEPTOSAR 200 SL in maize

Intended use **Active substance** **Application rate (g/ha)**		maize acetamiprid 60		
Nozzle reduction	**No spray buffer (m)**	20		
	Vegetated filter strip (m)	18 20	VFS mode	
			20	30
None	D3 ditch	0.02840	0.02840	0.01926
None	D4 pond	0.005452	0.005452	0.004151
None	D4 stream	0.03270	0.03270	0.02216
None	R1 pond	0.009102	0.005447	0.004147
None	R1 stream	0.1309	0.02501	0.01695
RAC (µg/L) **0.0235 (*Chirnomus rip.*)**		**PEC/RAC ratio**		
None	D3 ditch	**1.21**	**1.21**	0.82
None	D4 pond	0.23	-	-
None	D4 stream	**1.39**	**1.39**	0.94
None	R1 pond	0.39	-	-
None	R1 stream	**5.57**	**1.06**	0.72

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use		maize		
Active substance		acetamiprid		
Application rate (g/ha)		60		
Nozzle reduction	**No-spray buffer (m)**	20	50	20
	Vegetated filter strip (m)	20	20	VFS mode 20
None	D3 ditch	0.02840	**0.01176**	0.02840
50%		0.01420	**0.005878**	0.01420
None	D4 pond	0.005452	0.002841	0.005452
50%		0.002727	0.001421	0.002727
None	D4 stream	0.03270	0.01353	0.03270
50%		0.01634	0.006767	0.01634
None	R1 pond	0.009102	0.005931	0.005447
50%		0.006956	0.003429	0.002724
None	R1 stream	0.1309	0.1309	0.02501
50%		0.1309	0.1309	0.01250
RAC (µg/L) **0.0235 (*Chirnomus rip.*)**		**PEC/RAC ratio**		
None	D3 ditch	**1.21**	0.5	**1.21**
50%		0.60	-	0.60
None	D4 pond	0.23	-	0.23
50%		-	-	0.12
None	D4 stream	**1.39**	0.58	**1.39**
50%		0.70	-	0.70
None	R1 pond	0.39	-	0.23
50%		-	-	0.12
None	R1 stream	**5.57**	**5.57**	**1.06**
50%		**5.57**	**5.57**	0.53

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; values shaded in blue indicate the mitigation measure required

Table 9.5-6: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data with mitigation of spray drift and run-off for the use of LEPTOSAR 200 SL in winter cereals

~~**Intended use**~~	~~Winter cereals~~

Active substance **Application rate (g/ha)**		acetamiprid 40	
Nozzle reduction	**No-spray buffer (m)**	20	
	Vegetated filter strip (m)	18 20	VFS mode 20
None	D3 ditch	0.01895	0.01895
None	D4 pond	0.003632	0.003632
None	D4 stream	0.02006	0.02006
None	R1 pond	0.008973	0.003631
None	R1 stream	0.1372	0.01674
RAC (µg/L) **0.0235 (*Chirnomus rip.*)**		**PEC/RAC ratio**	
None	D3 ditch	0.81	-
None	D4 pond	0.15	-
None	D4 stream	0.85	-
None	R1 pond	0.38	-
None	R1 stream	**5.84**	0.71

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use **Active substance** **Application rate (g/ha)**		Winter cereals acetamiprid 40		
Nozzle reduction	**No-spray buffer (m)**	20	50	20
	Vegetated filter strip (m)	20	20	VFS mode 20
None	D3 ditch	0.01895	0.007846	0.01895
50%		0.009475	0.003923	
None	D4 pond	0.003632	0.001892	0.003632
50%		0.001816	0.000946	
None	D4 stream	0.02006	0.008305	0.02006
50%		0.01003	0.004154	
None	R1 pond	0.01811	0.007461	0.003631
50%		0.01196	0.006641	-
None	R1 stream	0.2728	0.1372	0.01674

50%		0.1372	0.1372	-
RAC (µg/L) **0.0235 (*Chirnomus rip.*)**				
None	D3 ditch	0.81	-	0.81
50%		-	-	-
None	D4 pond	0.15	-	0.15
50%		-	-	-
None	D4 stream	0.85	-	0.85
50%		-	-	-
None	R1 pond	0.77	-	0.15
50%		-	-	-
None	R1 stream	**11.61**	**5.84**	0.71
50%		**5.84**	**5.84**	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; values shaded in blue indicate the mitigation measure required

Table 9.5-7: **Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data with mitigation of spray drift and run-off for the use of LEPTOSAR 200 SL in winter oilseed rape**

~~**Intended use**~~ ~~**Active substance**~~ ~~**Application rate (g/ha)**~~		~~Winter oilseed rape~~ ~~acetamiprid~~ ~~60~~		
~~**Nozzle reduction**~~	~~**No-spray buffer (m)**~~	~~20~~		
	~~**Vegetated filter strip (m)**~~	~~18 20~~	~~VFS mode~~	
			~~20~~	~~30~~
~~None~~	~~D3 ditch~~	~~0.02833~~	~~0.02833~~	~~0.01921~~
~~None~~	~~D4 pond~~	~~0.005447~~	~~0.005447~~	~~0.004147~~
~~None~~	~~D4 stream~~	~~0.02857~~	~~0.02857~~	~~0.01936~~
~~None~~	~~R1 pond~~	~~0.005447~~	~~0.005447~~	~~0.004147~~
~~None~~	~~R1 stream~~	~~0.05109~~	~~0.02518~~	~~0.01706~~
~~**RAC (µg/L)**~~ ~~**0.0235 (*Chirnomus rip.*)**~~		~~**PEC/RAC ratio**~~		
~~None~~	~~D3 ditch~~	~~**1.21**~~	~~**1.21**~~	~~0.82~~
~~None~~	~~D4 pond~~	~~0.23~~	~~-~~	~~-~~
~~None~~	~~D4 stream~~	~~**1.22**~~	~~**1.22**~~	~~0.82~~
~~None~~	~~R1 pond~~	~~0.23~~	~~-~~	~~-~~
~~None~~	~~R1 stream~~	~~**2.17**~~	~~**1.22**~~	~~0.73~~

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use		Winter oilseed rape		
Active substance		acetamiprid		
Application rate (g/ha)		60		
Nozzle reduction	**No-spray buffer (m)**	20	50	20
	Vegetated filter strip (m)	20	20	VFS mode 20
None	D3 ditch	0.02833	0.01173	0.02833
50%		0.01417	0.005864	0.01417
None	D4 pond	0.005447	0.002837	0.005447
50%		0.002723	0.001418	0.002723
None	D4 stream	0.02857	0.01182	0.02857
50%		0.01428	0.005911	0.01428
None	R1 pond	0.005447	0.002837	0.005447
50%		0.002724	0.001541	0.002724
None	R1 stream	0.05109	0.05109	0.02518
50%		0.05109	0.05109	0.01258
RAC (µg/L) **0.0235 (*Chirnomus rip.*)**				
None	D3 ditch	**1.21**	0.49	**1.21**
50%		-	-	0.6
None	D4 pond	0.23	-	0.23
50%		-	-	-
None	D4 stream	**1.22**	0.50	**1.22**
50%		0.61	-	0.61
None	R1 pond	0.23	-	0.23
50%		-	-	-
None	R1 stream	**2.17**	**2.17**	**1.07**
50%		**2.17**	**2.17**	0.53

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; values shaded in blue indicate the mitigation measure required

Table 9.5-7: **Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data with mitigation of spray drift and run-off for the use of LEPTOSAR 200 SL in spring oilseed rape**

Intended use		Spring oilseed rape		
Active substance		acetamiprid		
Application rate (g/ha)		60		
Nozzle reduction	**No-spray buffer (m)**	20		
	Vegetated filter strip (m)	18-20	VFS mode	
			20	30
None	D3 ditch	0.02841	0.005447	0.01927
None	D4 pond	0.005449	0.005449	0.004149
None	D4 stream	0.03138	0.03138	0.02126
None	R1 pond	0.005447	0.005447	0.004147
None	R1 stream	0.02522	0.02522	0.01709
RAC (µg/L)		**PEC/RAC ratio**		
0.0235 (*Chirnomus rip.*)				
None	D3 ditch	**1.21**	**1.21**	0.82
None	D4 pond	0.23	0.23	0.18
None	D4 stream	**1.34**	**1.34**	0.90
None	R1 pond	0.23	0.23	0.18
None	R1 stream	**1.07**	**1.07**	0.73

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use		Spring oilseed rape	
Active substance		acetamiprid	
Application rate (g/ha)		60	
Nozzle reduction	**No-spray buffer (m)**	20	30
	Vegetated filter strip (m)	-	-
None	D3 ditch	0.02841	0.01927
None	D4 pond	0.005449	0.004149
None	D4 stream	0.03138	0.02126
None	R1 pond	0.005447	0.004147
None	R1 stream	0.02522	0.02180
RAC (µg/L)		**PEC/RAC ratio**	
0.0235 (*Chirnomus rip.*)			

None	D3 ditch	**1.21**	0.82
None	D4 pond	0.23	-
None	D4 stream	**1.34**	0.90
None	R1 pond	0.23	-
None	R1 stream	**1.07**	0.93

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; values shaded in blue indicate the mitigation measure required

Table 9.5-8: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data with mitigation of spray drift and run-off for the use of LEPTOSAR 200 SL in spring cereals

Intended use **Active substance** **Application rate (g/ha)**		Spring cereals acetamiprid 40	
Nozzle reduction	**No-spray buffer (m)**	10	20
	Vegetated filter strip (m)	-	-
None	D3 ditch	0.03640	0.01891
None	D4 pond	0.005440	0.003633
None	D4 stream	0.04017	0.02087
RAC (µg/L) **0.0235 (*Chirnomus rip*.)**		**PEC/RAC ratio**	
None	D3 ditch	**1.55**	0.80
None	D4 pond	0.23	-
None	D4 stream	**1.71**	0.89

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; values shaded in blue indicate the mitigation measure required

Table 9.5-9: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data with mitigation of spray drift and run-off for the use of LEPTOSAR 200 SL in pomefruits (Orchard)

~~**Intended use**~~ ~~**Active substance**~~ ~~**Application rate (g/ha)**~~		~~Pome fruits (Orchard)~~ ~~acetamiprid~~ ~~**2 x 25**~~	
~~**Nozzle reduction**~~	~~**No-spray buffer (m)**~~	~~**20**~~	
	~~**Vegetated filter**~~	~~**18-20**~~	~~**VFS mode**~~

	strip (m)		20	40	50
None	D3 ditch	0.1970	0.1970	0.03163	0.01749
None	D4 pond	0.03039	0.03039	0.007313	0.004494
None	D4 stream	0.2194	0.2194	0.03521	0.01947
None	R1 pond	0.03662	0.03662	0.008821	0.005422
None	R1 stream	0.2657	0.1740	0.02793	0.01544
RAC (µg/L) **0.0235 (*Chirnomus rip.*)**		**PEC/RAC ratio**			
None	D3 ditch	**8.38**	**8.38**	**1.35**	0.74
None	D4 pond	**1.29**	**1.29**	0.31	-
None	D4 stream	**9.34**	**9.34**	**1.50**	0.83
None	R1 pond	**1.56**	**1.56**	0.38	-
None	R1 stream	**11.31**	**7.40**	**1.19**	0.66

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use		Pome fruits (Orchard) – **BBCH 51**			
Active substance		Acetamiprid			
Application rate (g/ha)		**2 x 25**			
Nozzle reduction	**No-spray buffer (m)**	**20**	**80**	**20**	**50**
	Vegetated filter strip (m)	**20**	**20**	**VFS mode**	
				20	**20**
None	D3 ditch	0.1979	0.01757	0.1979	0.01757
50%		0.09895	0.002511	0.09895	0.008783
90 %		0.01979	0.000503	0.01979	-
None	D4 pond	0.02906	0.004299	0.02906	0.004299
50%		0.01451	0.000736	0.01451	0.002146
90 %		0.002892	0.000147	0.002892	-
None	D4 stream	0.2288	0.02031	0.2288	0.02031
50%		0.1144	0.002902	0.1144	0.01015
90 %		0.02288	0.000580	0.02288	-
None	R1 pond	0.03396	0.005026	0.03396	0.005026
50%		0.01696	0.000860	0.01696	0.002509
90 %		0.003381	0.000306	0.002288	-

Intended use		Pome fruits (Orchard) – **BBCH 51**			
Active substance		Acetamiprid			
Application rate (g/ha)		**2 x 25**			
Nozzle reduction	**No-spray buffer (m)**	**20**	**80**	**20**	**50**
	Vegetated filter strip (m)	**20**	**20**	**VFS mode**	
				20	**20**
None	R1 stream	0.1751	0.02501	0.1751	0.01554
50%		0.08754	0.02501	0.08754	0.007768
90 %		0.02501	0.02501	0.003381	-
RAC (µg/L) **0.0235 (*Chirnomus rip.*)**		**PEC/RAC ratio**			
None	D3 ditch	**8.42**	0.75	**8.42**	0.75
50%		**4.21**	-	**4.21**	-
90 %		0.84	-	0.84	-
None	D4 pond	**1.24**	0.18	**1.24**	0.18
50%		-	-	0.62	0.09
90 %		-	-	0.12	-
None	D4 stream	**9.74**	0.86	**9.74**	0.86
50%		**4.87**	-	**4.87**	-
90 %		0.97	-	0.97	-
None	R1 pond	**1.45**	0.21	**1.45**	0.21
50%		**3.73**	-	0.72	-
90 %		0.14	-	0.10	-
None	R1 stream	**7.45**	**1.06**	**7.45**	0.66
50%		**3.73**	**1.06**	**3.73**	-
90 %		**1.06**	**1.06**	0.14	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; values shaded in blue indicate the mitigation measure required

Table 9.5-10: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data with mitigation of spray drift and run-off for the use of LEPTOSAR 200 SL in pomefruits (Ornamental and nurseries)

~~**Intended use**~~		~~Pome fruits (Ornamental and nurseries)~~	
~~**Active substance**~~		~~acetamiprid~~	
~~**Application rate (g/ha)**~~		~~**50**~~	
~~**Nozzle reduction**~~	~~**No-spray buffer (m)**~~	~~**20**~~	
	~~**Vegetated filter**~~	~~**18 20**~~	~~**VFS mode**~~

	strip (m)		40	50	70
None	D3 ditch	0.4284	0.08248	0.04836	0.02159
None	D4 pond	0.04711	0.01327	0.008592	0.004350
None	D4 stream	0.4513	0.08692	0.05096	0.02275
None	R1 pond	0.04711	0.01327	0.008591	0.004350
None	R1 stream	0.3787	0.07294	0.04276	0.01909
RAC (µg/L) **0.0235 (*Chirnomus rip.*)**		**PEC/RAC ratio**			
None	D3 ditch	**18.23**	**3.51**	**2.06**	0.92
None	D4 pond	**2.00**	0.56	-	-
None	D4 stream	**19.20**	**3.70**	**2.17**	0.96
None	R1 pond	**2.00**	0.56	-	-
None	R1 stream	**16.11**	**3.10**	**1.82**	0.81

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-10a: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data with mitigation of spray drift and run-off for the use of LEPTOSAR 200 SL in pome fruits (Ornamental and nurseries)

Intended use **Active substance** **Application rate (g/ha)**		Pome fruits (Ornamental and nurseries) acetamiprid 40	
Nozzle reduction	**No-spray buffer (m)**	50	70
	Vegetated filter strip (m)	50	70
None	D3 ditch	0.03869	0.01727
None	D4 pond	0.006874	0.003480
None	D4 stream	0.04079	0.01820
None	R1 pond	0.006873	0.003480
None	R1 stream	0.03423	0.01527
RAC (µg/L) **0.0235 (*Chironomus rip.*)**		**PEC/RAC ratio**	
None	D3 ditch	**1.65**	0.73
None	D4 pond	0.30	-
None	D4 stream	**1.74**	0.77
None	R1 pond	0.30	-
None	R1 stream	**1.46**	0.65

Intended use		Pome fruits (Ornamental and nurseries)	
Active substance		acetamiprid	
Application rate (g/ha)		40	
Nozzle reduction	No-spray buffer (m)	20	30
	Vegetated filter strip (m)	20	20
None	D3 ditch	0.3428	0.1310
75%		0.08568	0.03276
90 %		0.03428	0.01310
None	D4 pond	0.03769	0.01825
75%		0.009421	0.004561
90 %		0.003768	0.001825
None	D4 stream	0.3611	0.1381
75%		0.09028	0.03452
90 %		0.03611	0.01381
None	R1 pond	0.03769	0.01825
75%		0.009420	0.004560
90 %		0.003768	0.001825
None	R1 stream	0.3030	0.1159
75%		0.07576	0.02897
90 %		0.03030	0.01159
RAC (µg/L) 0.0235 (*Chironomus rip.*)		PEC/RAC ratio	
None	D3 ditch	**14.59**	**5.57**
75%		**3.65**	**1.39**
90 %		**1.46**	0.56
None	D4 pond	**1.60**	0.78
75%		-	-
90 %		-	-
None	D4 stream	**15.37**	**5.88**
75%		**3.84**	**1.47**
90 %		**1.54**	0.59
None	R1 pond	**1.60**	0.78

75%		0.40	-
90 %		-	-
None	R1 stream	**12.89**	**4.93**
75%		**3.22**	**1.23**
90 %		**1.29**	0.49

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; values shaded in blue indicate the mitigation measure required

Table 9.5-11: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data with mitigation of spray drift and run-off for the use of LEPTOSAR 200 SL in pumpkin

~~**Intended use**~~ ~~**Active substance**~~ ~~**Application rate (g/ha)**~~		~~pumpkin~~ ~~acetamiprid~~ ~~60~~		
~~**Nozzle reduction**~~	~~**No spray buffer (m)**~~	~~20~~		
	~~**Vegetated filter strip (m)**~~	~~18 20~~	~~VFS mode~~	
			~~20~~	~~30~~
~~None~~	~~D3 ditch~~	~~0.02840~~	~~0.02840~~	~~0.01926~~
~~None~~	~~D4 pond~~	~~0.005447~~	~~0.005447~~	~~0.004147~~
~~None~~	~~D4 stream~~	~~0.02851~~	~~0.02851~~	~~0.01932~~
~~None~~	~~R1 pond~~	~~0.01055~~	~~0.005448~~	~~0.004148~~
~~None~~	~~R1 stream~~	~~0.1153~~	~~0.02531~~	~~0.01715~~
~~**RAC (µg/L)**~~ ~~**0.0235 (*Chirnomus rip.*)**~~		~~**PEC/RAC ratio**~~		
~~None~~	~~D3 ditch~~	~~**1.21**~~	~~**1.21**~~	~~0.82~~
~~None~~	~~D4 pond~~	~~0.23~~	~~-~~	~~-~~
~~None~~	~~D4 stream~~	~~**1.21**~~	~~**1.21**~~	~~0.82~~
~~None~~	~~R1 pond~~	~~0.45~~	~~-~~	~~-~~
~~None~~	~~R1 stream~~	~~**4.91**~~	~~**1.08**~~	~~0.73~~

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-12: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data with mitigation of spray drift and run-off for the use of LEPTOSAR 200 SL in sunflower

Intended use **Active substance** **Application rate (g/ha)**		Sunflower acetamiprid 50	
Nozzle reduction	**No-spray buffer (m)**	20	30
	Vegetated filter strip (m)	20	30
None	D3 ditch	0.0237	0.0237
None	D4 pond	0.0045	0.0035
None	D4 stream	0.0261	0.0177
None	R1 pond	0.0045	0.0035
None	R1 stream	0.0207	0.0140
RAC (µg/L) **0.0235 (*Chirnomus rip.*)**		**PEC/RAC ratio**	
None	D3 ditch	1.0	-
None	D4 pond	0.19	-
None	D4 stream	**1.11**	0.75
None	R1 pond	0.19	-
None	R1 stream	0.88	-

Intended use **Active substance** **Application rate (g/ha)**		Sunflower acetamiprid 50		
Nozzle reduction	**No-spray buffer (m)**	20	50	20
	Vegetated filter strip (m)	20	20	VFS mode 20
None	D3 ditch	0.02369	0.009809	0.0237
50%		0.01184	0.004903	0.01184
None	D4 pond	0.004541	0.002365	0.0045
50%		0.002270	0.001183	0.002270
None	D4 stream	0.02606	0.01079	0.0261
50%		0.01303	0.005393	0.01303
None	R1 pond	0.004629	0.002973	0.0045

50%		0.002901	0.002075	0.002269
None	R1 stream	0.05121	0.05121	0.0207
50%		0.05121	0.05121	0.01034
RAC (µg/L) **0.0235 (*Chirnomus rip.*)**				
None	D3 ditch	**1.00**	0.42	**1.0**
50%		0.50	-	0.50
None	D4 pond	0.19	-	0.19
50%		-	-	-
None	D4 stream	**1.11**	0.46	**1.11**
50%		0.55	-	0.55
None	R1 pond	0.20	-	0.20
50%		-	-	-
None	R1 stream	**2.18**	**2.18**	0.88
50%		**2.18**	**2.18**	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; values shaded in blue indicate the mitigation measure required

Table 9.5-13: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data with mitigation of spray drift and run-off for the use of LEPTOSAR 200 SL in soybean

~~**Intended use**~~ ~~**Active substance**~~ ~~**Application rate (g/ha)**~~		~~Soybean~~ ~~acetamiprid~~ ~~60~~	
~~**Nozzle reduction**~~	~~**No spray buffer (m)**~~	~~20~~	~~30~~
	~~**Vegetated filter strip (m)**~~	~~20~~	~~30~~
~~None~~	~~D3 ditch~~	~~0.0284~~	~~0.0193~~
~~None~~	~~D4 pond~~	~~0.0054~~	~~0.0041~~
~~None~~	~~D4 stream~~	~~0.0297~~	~~0.0201~~
~~None~~	~~R1 pond~~	~~0.0054~~	~~0.0041~~
~~None~~	~~R1 stream~~	~~0.0253~~	~~0.0171~~
~~**RAC (µg/L)**~~ ~~**0.0235 (*Chirnomus rip.*)**~~		~~**PEC/RAC ratio**~~	
~~None~~	~~D3 ditch~~	~~**1.21**~~	~~0.82~~
~~None~~	~~D4 pond~~	~~0.23~~	~~-~~

~~None~~	~~D4 stream~~	~~**1.26**~~	~~0.86~~
~~None~~	~~R1 pond~~	~~0.23~~	~~-~~
~~None~~	~~R1 stream~~	~~**1.08**~~	~~0.72~~

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use		Soybean	
Active substance		acetamiprid	
Application rate (g/ha)		60	
Nozzle reduction	**No-spray buffer (m)**	20	30
	Vegetated filter strip (m)	-	-
None	D3 ditch	0.02840	0.01925
50%		0.01420	-
None	D4 pond	0.005448	0.004148
50%		0.002724	-
None	D4 stream	0.02970	0.02013
50%		0.01484	-
None	R1 pond	0.005447	0.004147
50%		0.002724	-
None	R1 stream	0.02525	0.01711
50%		0.01685	-
RAC (µg/L)			
0.0235 (*Chirnomus rip.*)			
None	D3 ditch	**1.21**	0.82
50%		0.60	-
None	D4 pond	0.02	-
50%		-	-
None	D4 stream	**1.26**	0.86
50%		0.63	-
None	R1 pond	0.23	-
50%		-	-
None	R1 stream	**1.07**	0.72
50%		0.72	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; values shaded in blue indicate the mitigation measure required

Table 9.5-14: **Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data with mitigation of spray drift and run-off for the use of LEPTOSAR 200 SL in pumpkin at BBCH >50**

Intended use **Active substance** **Application rate (g/ha)**		Pumpkin (at BBCH >50) acetamiprid 60	
Nozzle reduction	**No-spray buffer (m)**	20	30
	Vegetated filter strip (m)	20	30
None	D3 ditch	0.0284	0.0193
None	D4 pond	0.0055	0.0042
None	D4 stream	0.0275	0.0186
None	R1 pond	0.0055	0.0041
None	R1 stream	0.0253	0.0172
RAC (µg/L) **0.0235 (*Chirnomus rip.*)**		**PEC/RAC ratio**	
None	D3 ditch	**1.21**	0.82
None	D4 pond	0.23	-
None	D4 stream	**1.17**	0.79
None	R1 pond	0.23	-
None	R1 stream	**1.08**	0.73

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use **Active substance** **Application rate (g/ha)**		Pumpkin (at BBCH >50) acetamiprid 60		
Nozzle reduction	**No-spray buffer (m)**	20	50	20
	Vegetated filter strip (m)	20	20	VFS mode 20
None	D3 ditch	0.02841	0.01176	0.0284
50%		0.01420	0.005880	0.01420
None	D4 pond	0.005461	0.002852	0.0055
50%		0.002739	0.001434	0.00275
None	D4 stream	0.02746	0.01137	0.0275
50%		0.01373	0.005694	0.01373
None	R1 pond	0.01604	0.01417	0.0055

50%		0.01409	0.01316	0.003541
None	R1 stream	0.1820	0.1820	0.0253
50%		0.1820	0.1820	0.01266
RAC (µg/L) **0.0235 (*Chirnomus rip.*)**		**PEC/RAC ratio**		
None	D3 ditch	**1.21**	0.50	**1.21**
50%		0.60	-	0.60
None	D4 pond	0.23	-	0.23
50%		-	-	-
None	D4 stream	**1.17**	0.48	**1.17**
50%		0.58	-	0.58
None	R1 pond	0.68	-	0.23
50%		-	-	-
None	R1 stream	**7.74**	**7.74**	**1.08**
50%		**7.74**	**7.74**	0.54

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; values shaded in blue indicate the mitigation measure required

Table 9.5-15: **Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data with mitigation of spray drift and run-off for the use of LEPTOSAR 200 SL in opium**

~~**Intended use**~~ ~~**Active substance**~~ ~~**Application rate (g/ha)**~~		~~opium~~ ~~acetamiprid~~ ~~30~~	
~~**Nozzle reduction**~~	~~**No-spray buffer (m)**~~	~~10~~	~~20~~
	~~**Vegetated filter strip (m)**~~	~~10~~	~~20~~
~~None~~	~~D3 ditch~~	~~0.0273~~	~~0.0142~~
~~None~~	~~D4 pond~~	~~0.0041~~	~~0.0027~~
~~None~~	~~D4 stream~~	~~0.0302~~	~~0.0157~~
~~None~~	~~R1 pond~~	~~0.0041~~	~~0.0027~~
~~None~~	~~R1 stream~~	~~0.0243~~	~~0.0126~~
~~**RAC (µg/L)**~~ ~~**0.0235 (*Chirnomus rip.*)**~~		~~**PEC/RAC ratio**~~	
~~None~~	~~D3 ditch~~	~~**1.16**~~	~~0.60~~

None	D4 pond	0.17	-
None	D4 stream	**1.29**	0.67
None	R1 pond	0.17	-
None	R1 stream	**1.03**	0.54

Intended use		opium	
Active substance		acetamiprid	
Application rate (g/ha)		30	
Nozzle reduction	**No-spray buffer (m)**	10	20
	Vegetated filter strip (m)	-	-
None	D3 ditch	0.02732	0.01420
None	D4 pond	0.004080	0.002725
None	D4 stream	0.03018	0.01568
None	R1 pond	0.004078	0.002724
None	R1 stream	0.02426	0.01260
RAC (µg/L)			
0.0235 (*Chirnomus rip.*)		**PEC/RAC ratio**	
None	D3 ditch	**1.16**	0.60
None	D4 pond	0.17	-
None	D4 stream	**1.28**	0.67
None	R1 pond	0.17	-
None	R1 stream	**1.03**	0.54

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; values shaded in blue indicate the mitigation measure required

Table 9.5-12: The risk assessment for aquatic species (most sensitive species of each group) for metabolites

Organism	Test substance	Use pattern	Toxicity endpoint mg/L	FOCUS Step 2 PECsw µg/L	RAC (AF = 100)	PEC/RAC	PEC/RAC<1
Fish	IM-1-4	Pome fruits (1 x 50g as/ha)	LC50 > 98.1 mg/L (*O. mykisss*)	2.29	981	0.00	YES
Invertebrates	IM-1-2	Pome fruits (1 x 50g as/ha)	LC50 = 15.0 mg/L (*Chironomus riparius*)	1.03	150	0.01	YES
	IM-1-4	Pome fruits (1 x 50g as/ha)	LC50 = 19 mg/L (*Mysidopsis bahia*)	2.29	190	0.01	YES
	IM-1-5	Spring oilseed rape	LC50 = 26 mg/L (*Daphnia*	0.30	260	0.00	YES

			magna)				
	IC 0	Pome fruits (1 x 50g as/ha)	LC50 > 95.1 mg /L ((*Daphnia magna*)	1.06	951	0.00	YES
	IB 1 1	Pome fruits (1 x 50g as/ha)	LC50 > 100 mg /L (*Chironomus riparius*)	1.68	1000	0.00	YES

RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

9.5.3 Overall conclusions

Performed risk evaluation demonstrated that following risk mitigation measures are deemed necessary to demonstrate acceptable risk to aquatic organisms following application of LEPTOSAR 200SL:

- For application in tomato (also *aubergine and paprika*): no mitigation measure required
- For application in **maize**: 20m non-sprayed buffer zone and 20m vegetated filter strip with 50 % nozzle reduction is required
- For application in **winter oilseed rape** and other minor uses crops (Flax, common hemp): 20m non-sprayed buffer zone and 20m vegetated filter strip with 50 % nozzle reduction is required.
- For application in **sunflowe**r: 20m non-sprayed buffer zone and 20m vegetated filter strip with 50 % nozzle reduction is required.
- For application in **winter cereals**: 20 m non-sprayed buffer zone and 20m vegetated filter strip is required
- For application **in pumpkin**: 20m non-sprayed buffer zone and 20m vegetated filter strip with 50 % nozzle reduction is required.
- For application in **soybean**: 20 m no-spray buffer zone with 50% nozzle reduction or 30m no-spray buffer zone is required.
- For application in **spring oilseed rape**: 30 m no-spray buffer zone is required.
- For application in **spring cereals**: 20 m no-spray buffer zone is required
- For application in **ornamental** and nurseries: 20 m vegetated buffer strip with 30m non-sprayed buffer zone and 90 % nozzle reduction is required.
- For application in **orchards** (crops i.e.: wild apple, pear, quince, sour cherry, peach, plum, nut, tobacco, common osier and purple willow): 20 m vegetated filter strip with 20m buffer zone and 90% nozzle reduction is required or 20 m vegetated filter strip with 50m non-sprayed buffer zone
- For application in **opium poppy**: 20 m no-spray buffer zone is required.

Review Comments:

The relevant predicted environmental concentrations in water (PEC_{sw}) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate). The initial risk assessment was based on the worst case PEC values and the results of laboratory toxicity testing. The PEC_{sw} Step 1-2 and Step 3 and 4 were used.

For FOCUS D3, D4 and R1scenarios, the LEPTOSAR 200 SL applications close to surface water pose acceptable risk to aquatic organisms with appropriate mitigation measures.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

~~Studies on the toxicity to bees have been carried out with acetamiprid. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).~~

Effects on bees of LEPTOSAR 200 SL were not evaluated as part of the EU assessment of acetamiprid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
~~Apis mellifera~~	~~acetamipryd~~	~~Oral~~	~~LD_{50} = 14.53 microg./bee (acetamiprid)~~	~~SANCO/1392/2001 – Final. 16 June 2004~~
~~Apis mellifera~~	~~acetamipryd~~	~~Contact~~	~~LD_{50} = 8.09 microg./bee (acetamiprid)~~	~~SANCO/1392/2001 – Final. 16 June 2004~~
~~Apis mellifera~~	~~acetamipryd~~	~~Chronic~~	~~10-d LC50 = 11.7 µg a.s./bee/day~~	~~EFSA, 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610, 91 pp. doi:10.2903/j.efsa.2016.4610~~
Apis mellifera	A-200SL-OR3-C	Oral	LD_{50} = 25.53 µg/bee (43.8 µg a.i./bee)	Mateusz Grzesica, 2019, B/56/18
Apis mellifera	A-200SL-OR3-C	Contact	LD = 50.00 µg/bee (85.7 µg a.i./bee)	Mateusz Grzesica, 2019, B/57/18
Apis mellifera	A-200SL-OR3-C	Chronic oral toxicity	LDD_{50} > 9.6 µg/bee/day NOEDD ≥ 9.6 µg/bee/day LC_{50} > 333 mg/kg NOEC = 167 mg/kg	Mateusz Grzesica, 2019, B/13/19
Apis mellifera	A-200SL-OR3-C	Larval toxicity test, repeated exposure	22-day EC_{50} = 2.5 µg test item/larva 22-day EC_{50} = 16.4 mg test item/kg of food 22-day NOEC < 7.1 mg test item/kg of food 22-day NOED <1.1 µg test item/larva	~~on-going study~~ Patrycja Holewik, 2021, B-56-21

9.6.1.1 Justification for new endpoints

To assess potential effects of LEPTOSAR 200 SL on bees, the studies were performed for this formulation and the results can be used for the risk assessment.

9.6.2 Risk assessment

Current risk assessment (European Commission, 2002b):
The evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

9.6.2.1 Hazard quotients for bees

The valid endpoints from the honeybee study conducted with A-200SL-OR3-C (formulation Leptosar 200SL) have been compared with the proposed single application rates to calculate hazard quotients in line with the current guidance document.
Hazard quotients were calculated for oral exposure (HQo) and contact exposure (HQc) for acetamiprid and for formulation LEPTOSAR 200 SL.
A Hazard Quotient of less than 50 indicates a low risk to bees in the field.

Table 9.6-2: First-tier assessment of the risk for bees due to the use of LEPTOSAR 200 SL in all intended uses major and minor acc. to the GAP table

~~**Intended use**~~ ~~**Active substance**~~ ~~**Application rate (g a.s/ha)**~~	~~All intended uses~~ ~~acetamiprid~~ ~~60~~		
~~**Test design**~~	~~**LD_{50} (lab.) (µg a.s/bee)**~~	~~**Single application rate (g a.s/ha)**~~	~~**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**~~
~~Oral toxicity~~	~~14.53~~	~~60~~	~~4.1~~
~~Contact toxicity~~	~~8.09~~		~~7.4~~
Product **Application rate (g product/ha)**	LEPTOSAR 200 SL 1 × 351.6 [a)]		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	25.53	351.6	13.8
Contact toxicity	50.00		7.0

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in **bold** breach the relevant trigger.
[a)] Based on a product density of 1.172 g/mL and an application rate of 0.3 L product/ha

Considering the higher application rates proposed in the GAP, the exposure does not pose any unacceptable risk on bees.

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant.

9.6.3 Effects on bumble bees

No data/information available.

9.6.4 Effects on solitary bees

No data/information available.

9.6.5 Overall conclusions

Considering the higher application rates proposed in the GAP, the exposure does not pose any unacceptable risk on bees. Both the acute oral exposure (HQo) and contact exposure (HQc) are acceptable following application of LEPTOSAR 200 SL in accordance with the proposed GAP without specific risk mitigation measures.

Review Comments:

The evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

The submitted risk assessment, based on laboratory studies, has been accepted. It can therefore be concluded that there will be negligible risk associated with the exposure of bees to LEPTOSAR 200 SL.

The applicant fulfilled the data requirements according to Commission regulation No. 284/2013 and submitted chronic tests on bees with formulated product.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

~~Studies on the toxicity to non-target arthropods have been carried out with acetamiprid. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).~~

Effects on non-target arthropods of LEPTOSAR 200 SL were not evaluated as part of the EU assessment of acetamiprid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.
The risk assessment was performed by Applicant for LEPTOSAR 200 SL in extended laboratory studies and also in age residue studies on *T. pyri*, *A. rhopalosiphi*, *Ch. carnea* and *C. septempunctata*

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
Aphidius rhopalosiphi	formulation	Extended laboratory test barley plants (3D)	LR_{50} = 36.2 mL/ha	Paweł Parma, 2019 B/09/19
Typhlodromus pyri	formulation	Extended laboratory	LR_{50} = 0.025 L/ha	Monika Stalmach,

Species	Substance	Exposure System	Results	Reference
		test bean leaf disc (2D)	ER_{50} > 0.02 L/ha	2019, B/10/19
Chrysoperla carnea	formulation	Extended laboratory test Rosa leaf disc (2D)	LR_{50} = 0.08 L/ha	Monika Stalmach, 2019, B/11/19
Coccinella septempunctata	formulation	Extended laboratory test Rosa leaf disc (2D)	LR_{50} = 0.032 L/ha	Monika Stalmach, 2019, B/12/19
Aphidius rhopalosiphi	formulation	Aged-residue test French bean plants (3D)	Mortality at 0.51 L/ha: 100 % at 0 DAT 100 % at 14 DAT 97.4 % at 28 DAT 97.4 % at 49 DAT 20.5 % at 77 DAT 13.2 % at 91 DAT	James Stevens, 2019, CIE-19-11
Typhlodromus pyri	formulation	Aged-residue test French bean plants (3D)	Mortality at 0.51 L/ha: 100 % at 0 DAT 3.5 % at 14 DAT 1.1 % at 28 DAT	Lisa Fallowfield, 2019, CIE-19-10
Chrysoperla carnea	formulation	Aged-residue test French bean plants (3D)	Mortality at 0.51 L/ha: 83.3 % at 0 DAT 55.0 % at 14 DAT 8.3 % at 28 DAT 7.9 % at 42 DAT	Russel Vaughan, 2019, CIE-19-13
Coccinella septempunctata	formulation	Aged-residue test French bean plants (3D)	Mortality at 0.51 L/ha: 100 % at 0 DAT 94.6 % at 14 DAT 36.7 % at 42 DAT 2.9 % at 56 DAT	Russel Vaughan, 2019, CIE-19-12

9.7.1.1 Justification for new endpoints

New studies with the formulation.
Risk assessment on non-target arthropods was carried out based on results obtained for LEPTOSAR 200 SL in extended laboratory studies and also in age residue studies on the test species : *T. pyri, A. rhopalosiphi, Ch. carnea* and *C. septempunctata*

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the

Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

In-field

Non-target arthropods living in the crop can be exposed to residues from formulation Leptosar 200 SL, which is applied at a maximum rate of 1 x 60 g a.s./ha (in oilseed rape and maize – major crops and in oilseed rape spring; flax; common hemp; soybean; sunflower seed; sugar maize, pumpkin, aubergine and paprika – as minor crops uses); 1 x 50 g a.s/ha in forest and ornamental nurseries- minor crops; 1 x 40 g a.s/ha in spring and winter cereals – as minor crop uses; 1 x 30 g a.s/ha in poppy seed – minor uses and 2 x 25 g a.s/ha (in wild apple, pear, chinese pear. Quince, sour cherry, sweet cherry, peach, nectarine, apricot, plum, hazelnuts, tobacco, common osier and purple willow- as minor crops uses). The maximum in-field exposure (Predicted Environmental Rate, PER) to foliar-dwelling arthropods is therefore 60 g a.s./ha, assuming the worst-case of 100% crop interception.

Exposure is not relevant for glasshouse uses – for tomato acc to GAP.

Table 9.7-2.1: Maximum in-field exposure value for application of Leptosar 200 SL

Substance	**Crop**	**Crop type acc. to BBA drift values tables[a)]**	**Application rate [g a.s./ha]**	**Foliar MAF**	**Foliar in-field PERmax [g a.s./ha]**
Leptosar 200 SL	Oilseed rape winter; Maize	Field crop	1 x 60	1	60
	Oilseed rape spring; Flax; Common hemp; Soybean; Sunflower seed; Sugar maize;	Field crop	1 x 60	1	60
	Spring rye ; Spring triticale; Durum wheat; Spelt wheat; einkorn wheat; emmer wheat; Spring barley; Winter barley; Spring wheat; Winter wheat; Winter triticale; Winter rye;	Field crop	1 x 40	1	40
	Poppy seed	Field crop	1 x 30	1	30
	Pumpkin; Aubergine; Paprika	Vegetables/ Ornamentals/ Small fruit (<50cm)	1 x 60	1	60
	Wild apple; Pear; Chinese pear; Quince; Sour cherry; Sweet cherry; Peach;	Fruit crops, early	2 x 25	1.7	42.5

	Nectarine; Apricot; Plum; Hazelnut; Walnut; Tobacco; Common osier; Purple willow				
	Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations	Fruit crops, early	1 x 50	1	50

a) Drift values tables according to BBA (Federal Biological Agency of Agriculture and Forestry, Germany), 2000: Bekanntmachung des Verzeichnisses risikomindernder Anwendungsbedingungen für Nichtzielorganismen. Bundesanzeiger 100: 9878-9880.

Off-field

Risk assessment of areas immediately surrounding the crop is considered important since these areas represent a natural reservoir for immigration, emigration and reproduction of arthropod populations and provide increased species diversity. Exposure of non-target arthropods living in off-field areas to Leptosar 200 SL will mainly be due to spray drift from field applications. Off-field PERmax (predicted environmental rate) was calculated from the application rate in conjunction with drift values published by the BBA (2000)

Exposure is not relevant for glasshouse uses – for tomato acc to GAP.

Table 9.7-2.2: Maximum off-field foliar exposure for application of Leptosar 200 SL

Substance	**Crop**	**Crop type acc. to BBA drift values tables[a)]**	**Foliar in-field PERmax [g a.s./ha]**	**Drift factor (%drift/100)**	**VDF[b)]**	**Off-field PERmax [g a.s./ha]**
Leptosar 200 SL	Oilseed rape winter; Maize	Field crop	60	0.0277	5	0.3324
	Oilseed rape spring; Flax; Common hemp; Soybean; Sunflower seed; Sugar maize;	Field crop	60	0.0277	5	0.3324
	Spring rye ; Spring triticale; Durum wheat; Spelt wheat; einkorn wheat; emmer wheat; Spring barley; Winter barley; Spring wheat;	Field crop	40	0.0277	5	0.2216

	Winter wheat; Winter triticale; Winter rye;					
	Poppy seed	Field crop	30	0.0277	5	0.1662
	Pumpkin; Aubergine; Paprika	Vegetables/ Ornamentals/ Small fruit (<50cm)	60	0.0277	5	0.3324
	Wild apple; Pear; Chinese pear; Quince; Sour cherry; Sweet cherry; Peach; Nectarine; Apricot; Plum; Hazelnut; Walnut; Tobacco; Common osier; Purple willow	Fruit crops, early	42.5	0.2553	5	2.17
	Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations	Fruit crops, early	50	0.2920	5	2.92

a) Drift values tables according to BBA (Federal Biological Agency of Agriculture and Forestry, Germany), 2000: Bekanntmachung des Verzeichnisses risikomindernder Anwendungsbedingungen für Nichtzielorganismen. Bundesanzeiger 100: 9878-9880.
b) vdf: Vegetation distribution factor; In accordance with EFSA (2019), Technical report on the outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2019:EN-1673. 117 pp. doi:10.2903/sp.efsa.2019.EN-1673.

9.7.2.1 Risk assessment for in-field exposure

The risk to non-target arthropods is assessed using the approach recommended in the published *ESCORT 2 document (Candolfi et al. 2001)* and the *SANCO/10329/2002*.

In-field
The potential risk of Leptosar 200 SL to in-field non-target arthropods was assessed by calculation of the hazard quotient (HQ = exposure/toxicity) with the predicted environmental rate (PER) and the lowest lethal rate (LR_{50}) values ~~according to the following formula:~~

The HQ trigger for Tier II extended laboratory studies is 1. The resulting HQin-field values are presented, in table below.

Table 9.7-2.1.1: Higher-tier assessment of the in-field risk for non-target arthropods due to the use of LEPTOSAR 200 SL – acc. to the GAP table

Species	LR_{50} [g a.s/ha]	Crop	Crop type acc. to BBA drift values tables	Application rate [g a.s./ha]	Foliar MAF	Foliar in-field PERmax [g a.s./ha]	HQ in-field	Trigger value
Typhlodromus pyri Tier II,	5.04	Oilseed rape winter; Maize	Field crop	1 x 60	1	60	**11.9**	1
		Oilseed rape spring; Flax; Common hemp; Soybean; Sunflower seed; Sugar maize;	Field crop					
		Spring rye ; Spring triticale; Durum wheat; Spelt wheat; einkorn wheat; emmer wheat; Spring barley; Winter barley; Spring wheat; Winter wheat; Winter triticale; Winter rye;	Field crop	1 x 40		40	**7.93**	
		Poppy seed	Field crop	1 x 30		30	**5.95**	
		Pumpkin; Aubergine; Paprika	Vegetables/ Ornamentals/ Small fruit (<50cm)	1 x 60		60	**11.9**	
		Wild apple; Pear; Chinese pear; Quince; Sour cherry; Sweet	Fruit crops, early	2 x 25	1.7	42.5	**8.43**	

		cherry; Peach; Nectarine; Apricot; Plum; Hazelnut; Walnut; Tobacco; Common osier; Purple willow						
		Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations	Fruit crops, early	1 x 50	1	50	**9.92**	
Aphidius rhopalosiphi, Tier II	7.30	Oilseed rape winter; Maize	Field crop	1 x 60	1	60	**8.21**	1
		Oilseed rape spring; Flax; Common hemp; Soybean; Sunflower seed; Sugar maize;	Field crop					
		Spring rye ; Spring triticale; Durum wheat; Spelt wheat; einkorn wheat; emmer wheat; Spring barley; Winter barley; Spring wheat; Winter wheat;	Field crop	1 x 40		40	**5.47**	

		Winter triticale; Winter rye;						
		Poppy seed	Field crop	1 x 30		30	**4.10**	
		Pumpkin; Aubergine; Paprika	Vegetables/ Ornamentals/ Small fruit (<50cm)	1 x 60		60	**8.21**	
		Wild apple; Pear; Chinese pear; Quince; Sour cherry; Sweet cherry; Peach; Nectarine; Apricot; Plum; Hazelnut; Walnut; Tobacco; Common osier; Purple willow	Fruit crops, early	2 x 25	1.7	42.5	**5.82**	
		Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations	Fruit crops, early	1 x 50	1	50	**6.85**	
Chrysoperla carnea Tier II	16.5	Oilseed rape winter; Maize	Field crop	1 x 60	1	60	**3.63**	1
		Oilseed rape spring; Flax; Common hemp; Soybean; Sunflower seed; Sugar maize;	Field crop					

		Spring rye ; Spring triticale; Durum wheat; Spelt wheat; einkorn wheat; emmer wheat; Spring barley; Winter barley; Spring wheat; Winter wheat; Winter triticale; Winter rye;	Field crop	1 x 40		40	**2.42**	
		Poppy seed	Field crop	1 x 30		30	**1.81**	
		Pumpkin; Aubergine; Paprika	Vegetables/ Ornamentals/ Small fruit (<50cm)	1 x 60		60	**3.63**	
		Wild apple; Pear; Chinese pear; Quince; Sour cherry; Sweet cherry; Peach; Nectarine; Apricot; Plum; Hazelnut; Walnut; Tobacco; Common osier; Purple willow	Fruit crops, early	2 x 25	1.7	42.5	**2.57**	
		Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas	Fruit crops, early	1 x 50	1	50	**3.03**	

		trees grown on plantations						
Coccinella septempunctata Tier II	6.45	Oilseed rape winter; Maize	Field crop	1 x 60	1	60	**9.30**	1
		Oilseed rape spring; Flax; Common hemp; Soybean; Sunflower seed; Sugar maize;	Field crop					
		Spring rye ; Spring triticale; Durum wheat; Spelt wheat; einkorn wheat; emmer wheat; Spring barley; Winter barley; Spring wheat; Winter wheat; Winter triticale; Winter rye;	Field crop	1 x 40		40	**6.20**	
		Poppy seed	Field crop	1 x 30		30	**4.65**	
		Pumpkin; Aubergine; Paprika	Vegetables/ Ornamentals/ Small fruit (<50cm)	1 x 60		60	**9.30**	
		Wild apple; Pear; Chinese pear; Quince; Sour cherry; Sweet cherry; Peach; Nectarine; Apricot; Plum; Hazelnut;	Fruit crops, early	2 x 25	1.7	42.5	**6.59**	

		Walnut; Tobacco; Common osier; Purple willow						
		Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations	Fruit crops, early	1 x 50	1	50	**7.75**	

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient.
Criteria values shown in **bold** breach the relevant trigger.
* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

Based on results obtained for LEPTOSAR 200 SL in extended laboratory studies the corresponding "in-field" hazard quotients are above the trigger value of 1 indicating an unacceptable "in-field" risk to non-target arthropods, following application of LEPTOSAR 200 SL according to the proposed GAP.
In connection with that and to complete risk assessment for non-target arthropods Applicant decided to conduct additional studies. Additional studies will include aged residue studies on *Typhlodromus pyri Aphidius rhopalosiphi, Chrysoperla carnea,* and *Coccinella septempunctata* for plant protection product LEPTOSAR 200 SL.

9.7.2.2 Risk assessment for off-field exposure

Risk assessment of areas immediately surrounding the crop is considered important since these areas represent a natural reservoir for immigration, emigration and reproduction of arthropod populations and provide increased species diversity. Exposure of non-target arthropods living in off-field areas to Leptosar 200 SL will mainly be due to spray drift from field applications. Off-field areas are assumed to be densely vegetated and thus spray drift is unlikely to reach bare ground. Therefore, evaluation of exposure via soil residues in off-field areas was not considered. Off-field foliar PER values were calculated from in-field foliar PERs in conjunction with drift values published by the BBA (2000) as shown in the following equation:

$$\text{Off - field foliar PER} = \frac{\text{Maximum in - field foliar PER x (\% drift/100)}}{\text{vegetation distributi on factor}}$$

Vegetation distribution factor: Currently, a VDF of 10 is used in the risk assessment for NTAs as proposed by the report of the SETAC/ESCORT 2 Workshop (Candolfi at al., 2001) based on 'leaf area indices' and 'plant interception'. According to (European Commission, 2002)* 'this figure is considered unreliable, therefore more appropriate data should be used as soon as they become available'.
Several reviews of the VDF value and attempts to derive an appropriate default figure for the VDF are available and all these evaluations were presented in Appendix E of the EFSA scientific opinion on NTAs

(EFSA PPR Panel, 2015)**. These reviews indicate that a VDF of 10 is not appropriate. Thus according to EFSA (2019)*** the majority of the experts agreed on the recommendation of using a VDF of 5 for all the tiers of the assessment.

The drift value at 3 m distance for two application is 25.53% of the application rate (82 th percentile drift). The drift factor (% drift/100) is therefore 25.53/100 = 0.2553 for fruit crops, early scenario.

The drift value at 3 m distance for one application is 29.20% of the application rate (82 th percentile drift). The drift factor (% drift/100) is therefore 29.20/100 = 0.2920 for fruit crops, early scenario.

The drift value at 1 m distance is 2.77% of the application rate (90th percentile drift). The drift factor (% drift/100) is therefore 2.77/100 = 0.0277 for field crops scenario.

The resulting PERoff-field values are shown in table below.

Table 9.7-2.2.1: Higher-tier assessment of the off-field risk for non-target arthropods due to the use of LEPTOSAR 200 SL all crops scenario

Species	LR_{50} [g a.s/ha]	Crop	Crop type acc. to BBA drift values tables[a)]	Drift factor (%drift/100)	Off-field PERmax [g a.s/ha]	CF	HQoff-field	Trigger value
Typhlodromus pyri Tier II,	5.04	Oilseed rape winter; Maize	Field crop	0.0277 @1m	0.3324	5	0.33	1
		Oilseed rape spring; Flax; Common hemp; Soybean; Sunflower seed; Sugar maize;	Field crop	0.0277 @1m	0.3324		0.33	
		Spring rye ; Spring triticale; Durum wheat; Spelt wheat; einkorn wheat; emmer wheat; Spring barley; Winter barley; Spring wheat; Winter wheat; Winter triticale;	Field crop	0.0277 @1m	0.2216		0.22	

		Winter rye;						
		Poppy seed	Field crop	0.0277 @1m	0.1662		0.16	
		Pumpkin; Aubergine; Paprika	Vegetables/ Ornamentals/ Small fruit (<50cm)	0.0277 @1m	0.3324		0.33	
		Wild apple; Pear; Chinese pear; Quince; Sour cherry; Sweet cherry; Peach; Nectarine; Apricot; Plum; Hazelnut; Walnut; Tobacco; Common osier; Purple willow	Fruit crops, early	0.2553 @3m	2.17		**2.15**	
		Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations	Fruit crops, early	0.2920 @3m	2.92		**2.89**	
Aphidius rhopalosiphi, Tier II (3D)	7.30	Oilseed rape winter; Maize,	Field crop	0.0277 @1m	~~0.3324~~ 1.662	5	~~0.22~~ **1.14**	1
		Oilseed rape spring; Flax; Common hemp; Soybean; Sunflower seed; Sugar maize;	Field crop	0.0277 @1m	~~0.3324~~ 1.662		~~0.22~~ **1.14**	
		Spring rye ; Spring	Field crop	0.0277 @1m	~~0.2216~~		~~0.15~~	

		triticale; Durum wheat; Spelt wheat; einkorn wheat; emmer wheat; Spring barley; Winter barley; Spring wheat; Winter wheat; Winter triticale; Winter rye;			1.108		0.76	
		Poppy seed	Field crop	0.0277 @1m	~~0.1662~~ 0.831		~~0.11~~ 0.57	
		Pumpkin; Aubergine; Paprika	Vegetables/ Ornamentals/ Small fruit (<50cm)	0.0277 @1m	~~0.3324~~ 1.662		~~0.22~~ **1.14**	
		Wild apple; Pear; Chinese pear; Quince; Sour cherry; Sweet cherry; Peach; Nectarine; Apricot; Plum; Hazelnut; Walnut; Tobacco; Common osier; Purple willow	Fruit crops, early	0.2553 @3m	~~2.17~~ 10.85		~~**1.48**~~ **7.43**	
		Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas	Fruit crops	0.2920 @3m	~~2.92~~ 14.6		~~**2.0**~~ **10**	

		trees grown on plantations						
Chrysoperla carnea Tier II	16.5	Oilseed rape winter; Maize	Field crop	0.0277 @1m	0.3324	5	0.10	1
		Oilseed rape spring; Flax; Common hemp; Soybean; Sunflower seed; Sugar maize;	Field crop	0.0277 @1m	0.3324		0.10	
		Spring rye ; Spring triticale; Durum wheat; Spelt wheat; einkorn wheat; emmer wheat; Spring barley; Winter barley; Spring wheat; Winter wheat; Winter triticale; Winter rye;	Field crop	0.0277 @1m	0.2216		0.06	
		Poppy seed	Field crop	0.0277 @1m	0.1662		0.05	
		Pumpkin; Aubergine; Paprika	Vegetables/ Ornamentals/ Small fruit (<50cm)	0.0277 @1m	0.3324		0.10	
		Wild apple; Pear; Chinese pear; Quince; Sour cherry; Sweet cherry; Peach; Nectarine; Apricot; Plum; Hazelnut;	Fruit crops, early	0.2553 @3m	2.17		0.65	

		Walnut; Tobacco; Common osier; Purple willow						
		Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations	Fruit crops, early	0.1573 @3m	2.92		0.88	
Coccinella septempunctata Tier II	6.45	Oilseed rape winter; Maize	Field crop	0.0277 @1m	0.3324	5	0.25	1
		Oilseed rape spring; Flax; Common hemp; Soybean; Sunflower seed; Sugar maize;	Field crop	0.0277 @1m	0.3324		0.25	
		Spring rye ; Spring triticale; Durum wheat; Spelt wheat; einkorn wheat; emmer wheat; Spring barley; Winter barley; Spring wheat; Winter wheat; Winter triticale; Winter rye;	Field crop	0.0277 @1m	0.2216		0.17	
		Poppy seed	Field crop	0.0277 @1m	0.1662		0.12	

		Pumpkin; Tomato; Aubergine; Paprika	Vegetables/ Ornamentals/ Small fruit (<50cm)	0.0277 @1m	0.3324		0.25	
		Wild apple; Pear; Chinese pear; Quince; Sour cherry; Sweet cherry; Peach; Nectarine; Apricot; Plum; Hazelnut; Walnut; Tobacco; Common osier; Purple willow	Fruit crops, early	0.2553 @3m	2.17		**1.68**	
		Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations	Fruit crops, early	0.2920 @3m	2.92		**2.26**	

PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in **bold** breach the relevant trigger.
If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.
* European Commission, 2002. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002-rev. 2 final, 17 October 2002
** EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2015. Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target arthropods. EFSA Journal 2015;13(2):3996, 212 pp. doi:10.2903/j.efsa.2015.3996
***In accordance with EFSA (2019). Technical report on the outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2019:EN-1673. 117 pp. doi:10.2903/sp.efsa.2019.EN-1673.

For *Cocinella septempunctata* the off-field HQ values are below the relevant trigger of 1 for all scenarios indicating acceptable risk.

For *Typhlodromus pyri*, *Aphidius rhopalosiphi*, and *Chrysoperla carnea* the off-field HQ values were higher than the relevant trigger of 1. This indicates that Leptosar 200 SL poses a potential risk to off-field non-target arthropods following application according to the proposed use patterns in fruit crops scenario.

The results of the risk assessment using typical mitigation measures (drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarized and conducted in Table 9.7-4.

9.7.2.3 Additional higher-tier risk assessment

To complete "in-field" risk assessment for non-target arthropods additional higher tier studies named age residue on *T. pyri, A. rhopalosiphi, Ch. carnea* and *C. septempunctata* were performed.

- The effects of freshly-dried and field-aged foliar residues of A-200SL-OR3-C on the predatory mite *Typhlodromus pyri* were evaluated under extended laboratory test conditions. When applied to dwarf French bean plants at a rate equivalent to 0.51 L product/ha (nominally 102 g a.s./ha), both 14-day-old and 28-day field-aged residues resulted in no unacceptable effects on either the survival or the subsequent reproductive capacity of the mites.
  In terms of the in-field risk, acceptable effects were noted after 14 and 28 days at 0.51 L product/ha. In-field recovery is expected within this time scale (14 - 28 days).
- The effects of freshly-dried and field-aged foliar residues of A-200SL-OR3-C on the parasitic wasp, *Aphidius rhopalosiphi* were evaluated under extended laboratory test conditions. When applied to dwarf French bean plants at a rate equivalent to 0.51 L product/ha, both 77-day and 91-day field-aged residues resulted in no unacceptable effects on either the survival or the subsequent reproductive capacity of the wasps.
  In terms of the in-field risk, acceptable effects were noted after 77 and 91 days at 0.51 L product/ha. In-field recovery is expected within this time scale (77 - 91 days).
- The effects of both fresh and aged foliar residues of A-200SL-OR3-C on the green lacewing, *Chrysoperla carnea*, were evaluated under extended laboratory conditions. When applied at a rate equivalent to 0.51 L product/ha, fresh (0-day-old) and 14-day-old foliar residues of A-200SL-OR3-C had unacceptable effects on the survival of the lacewings. However, both 28-day-old and 42-day-old residues resulted in no unacceptable effects on either the survival or the subsequent reproductive capacity of the lacewings.
  In terms of the in-field risk, acceptable effects were noted after 28 and 42 days at 0.51 L product/ha. In-field recovery is expected within this time scale (28 - 42 days).
- The effects of both fresh and aged foliar residues of A-200SL-OR3-C on the ladybird beetle, *Coccinella septempunctata*, were evaluated under extended laboratory conditions. When applied at a rate equivalent to 0.51 L product/ha, fresh (0-day-old) and 14-day-old foliar residues of A-200SL-OR3-C had unacceptable effects on the survival. However, both 42-day-old and 56-day-old residues resulted in no unacceptable effects on either the survival or the subsequent reproductive capacity of the ladybirds.
  In terms of the in-field risk, acceptable effects were noted after 42 and 56 days at 0.51 L product/ha. In-field recovery is expected within this time scale (42 - 56 days).

9.7.2.4 Risk mitigation measures

In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures are summarised in the following table.

Table 9.7-2.1: Assessment of the off-field risk for non-target arthropods due to the use of Leptosar 200 SL in forest and ornamental nurseries plants …(fruit crops, late scenario, one application) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use **Active substance/product** **Application rate (g a.s/ha)** **MAF** **vdf**		Forest and ornamental nurseries plants …/ Fruit crops, early scenario Leptosar 200 SL 1 x 50 1 5			
Buffer strip (m)	**Drift rate (%)**	**corr. $PER_{off\text{-}field}$ (g/ha)**	**corr. $PER_{off\text{-}field}$ 50 % drift red. (g/ha)**	**corr. $PER_{off\text{-}field}$ 75 % drift red. (g/ha)**	**corr. $PER_{off\text{-}field}$ 90 % drift red. (g/ha)**
3	29.20	2.92	1.46	0.73	0.29
5	19.89	1.98	0.99	0.49	0.19
10	11.81	1.18	0.59	0.29	0.11
Tier 2 toxicity value LR_{50} = 5.04 g a.s/ha		**$HQ_{off\text{-}field}$** **criterion: HQ ≤ 1**			
3		**2.89**	**1.45**	0.72	0.28
5		**1.96**	0.98	0.48	0.18
10		**1.17**	0.58	0.28	0.10

Table 9.7-3.2: Assessment of the off-field risk for non-target arthropods due to the use of Leptosar 200 SL in fruit crops, early scenario, two application considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use **Active substance/product** **Application rate (g a.s/ha)** **MAF** **vdf**		Apple, Pear… Fruit crops, early scenario Leptosar 200 SL 2 x 25 1.7 5			
Buffer strip (m)	**Drift rate (%)**	**corr. $PER_{off\text{-}field}$ (g/ha)**	**corr. $PER_{off\text{-}field}$ 50 % drift red. (g/ha)**	**corr. $PER_{off\text{-}field}$ 75 % drift red. (g/ha)**	**corr. $PER_{off\text{-}field}$ 90 % drift red. (g/ha)**
3	25.53	2.17	1.08	0.54	0.21
5	16.87	1.43	0.72	0.35	0.14
10	9.61	0.82	0.41	0.20	0.08
Tier 2 toxicity value LR_{50} = 5.04 g a.s/ha		**$HQ_{off\text{-}field}$** **criterion: HQ ≤ 1**			
3		**2.15**	**1.07**	0.53	0.21
5		**1.41**	0.70	0.35	0.14
10		0.81	0.40	0.20	0.08

~~The risks for NTA are therefore considered acceptable with the following mitigation measures:~~

~~For crops: fruit crops, early scenario (one and two application) the following buffer zone to non agriculture land should be applied:~~

- ~~75% drift reducing nozzles are required when a no spray buffer zone of 3 m is respected~~
- ~~50% drift reducing nozzles are required when a no-spray buffer zone of 5 m is respected.~~

The off-risk assessment for *A. rhopalosipi*

Intended use		Wild apple; Pear; Chinese pear; Quince; Sour cherry; Sweet cherry; Peach; Nectarine; Apricot; Plum; Hazelnut; Walnut; Tobacco; Common osier; Purple willow			
Active substance/product		Leptosar 200 SL			
Application rate (g a.s/ha)		2 x 25			
MAF		1.7			
vdf		1			
Buffer strip (m)	**Drift rate (%)**	**corr. PER$_{off-field}$ (g/ha)**	**corr. PER$_{off-field}$ 50 % drift red. (g/ha)**	**corr. PER$_{off-field}$ 75 % drift red. (g/ha)**	**corr. PER$_{off-field}$ 90 % drift red. (g/ha)**
3	25.53	54.25	27.13	13.56	5.43
5	16.87	35.75	17.87	8.94	-
10	9.61	20.25	10.12	5.06	-
15	5.61	11.92	5.96	-	-
20	2.59	5.50	-	-	-
Tier 2 toxicity value		**HQ$_{off-field}$**			
LR_{50} = 7.3 g a.s/ha		**criterion: HQ ≤ 1**			
3		**No**	**No**	**No**	Yes
5		**No**	**No**	**No**	-
10		**No**	**No**	Yes	-
15		**No**	Yes	-	-
20		Yes	-	-	-

Intended use		Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations			
Active substance/product		Leptosar 200 SL			
Application rate (g a.s/ha)		1 x 50			
MAF		1			
vdf		1			
Buffer strip (m)	**Drift rate (%)**	**corr. PER$_{off-field}$ (g/ha)**	**corr. PER$_{off-field}$ 50 % drift red. (g/ha)**	**corr. PER$_{off-field}$ 75 % drift red. (g/ha)**	**corr. PER$_{off-field}$ 90 % drift red. (g/ha)**
3	29.20	73.0	36.5	18.25	7.3
5	19.89	49.72	24.86	12.43	-
10	11.81	29.52	14.76	7.38	-

15	5.55	13.87	6.94	-	-
20	2.77	6.92	-	-	-
Tier 2 toxicity value LR_{50} = 7.3 g a.s/ha		**$HQ_{off-field}$** **criterion: HQ ≤ 1**			
3		**No**	**No**	**No**	Yes
5		**No**	**No**	**No**	-
10		**No**	**No**	**No**	-
15		**No**	Yes	-	-
20		Yes	-	-	-

The risk assessment for *A. rhopalosiphi* due to the change in application rate for Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations. The application rate was decrease to 40 g/ha.

Intended use	Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations				
Active substance/product	Leptosar 200 SL				
Application rate (g a.s/ha)	1 x 40				
MAF	1				
vdf	1				
Buffer strip (m)	Drift rate (%)	corr. PERoff-field (g/ha)	corr. PERoff-field 50 % drift red. (g/ha)	corr. PERoff-field 75 % drift red. (g/ha)	PERoff-field 90 % drift red. (g/ha)
3	29.20	58.4	29.2	14.6	5.84
5	19.89	39.78	19.89	9.945	3.978
10	11.81	23.62	11.81	5.905	2.362
15	5.55	11.1	5.55	2.775	1.11
20	2.77	5.54	2.77	1.385	0.554
Tier 2 toxicity value LR50 = 7.3 g a.s/ha		HQoff-field criterion: HQ ≤ 1			
3		No	No	No	Yes
5		No	No	No	-
10		No	No	Yes	-
15		No	Yes	-	-
20		Yes	-	-	-

Intended use		Oilseed rape, maize, flax, hemp, soybean, sunflower, pumpkin, ornamentals < 50cm			
Active substance/product		Leptosar 200 SL			
Application rate (g a.s/ha)		1 x 60			
MAF		1			
vdf		1			
Buffer strip (m)	**Drift rate (%)**	**corr. $PER_{off-field}$ (g/ha)**	**corr. $PER_{off-field}$ 50 % drift red. (g/ha)**	**corr. $PER_{off-field}$ 75 % drift red. (g/ha)**	**corr. $PER_{off-field}$ 90 % drift red. (g/ha)**

1	2.77	8.31	4.15	-	-
5	0.57	1.71	-	-	-
Tier 2 toxicity value LR_{50} = 7.3 g a.s/ha		**$HQ_{off-field}$** **criterion: HQ ≤ 1**			
1		**No**	Yes	-	
5		Yes	-	-	-

9.7.3 Overall conclusions

Applicant decided to start the studies on arthropods from extended laboratory studies because predicted unsatisfactory results in Tier I (laboratory studies on glass plate).

Based on results obtained for LEPTOSAR 200 SL in extended laboratory studies (Tier II) on *T. pyri, A. rhopalosiphi, Ch. carnea* and *C. septempunctata* the corresponding "in-field" hazard quotients are above the trigger value of 1 indicating an unacceptable "in-field" risk to non-target arthropods, following application of LEPTOSAR 200 SL according to the proposed GAP.

~~Performed risk assessment for the "off-field" exposure demonstrated that formulation Leptosar 200 SL poses unacceptable risk to off-field population of non-target arthropods after use in crops grouping in "fruit crops scenario" one and two application. For these crops an acceptable risk is indicated when the risk mitigation measure (75% drift reducing nozzles are required when a no spray buffer zone of 3 m is respected or 50% drift reducing nozzles are required when a no spray buffer zone of 5 m is respected) is applied.~~

The available data on aged residue studies indicate that, any initial effects on non-target arthropods from the proposed uses of LEPTOSAR 200 SL will be short-lived and recovery/recolonisation will take place within an acceptable time frame, thus an acceptable in field risk can be concluded.

The risks for NTA are therefore considered acceptable with the following mitigation measures:
-Wild apple; Pear; Chinese pear; Quince; Sour cherry; Sweet cherry; Peach; Nectarine; Apricot; Plum; Hazelnut; Walnut; Tobacco; Common osier; Purple willow – 2 x 25g a.s./ha:

- 90%-drift reducing nozzles are required when a no-spray buffer zone of 3 m is respected
- 75%-drift reducing nozzles are required when a no-spray buffer zone of 10 m is respected
- 50%-drift reducing nozzles are required when a no-spray buffer zone of 15 m is respected
- a no-spray buffer zone of 20 m is respected

- Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations- 1 x 40 g a.s./ha:

- 90%-drift reducing nozzles are required when a no-spray buffer zone of 3 m is respected
- 75%-drift reducing nozzles are required when a no-spray buffer zone of 10 m is respected
- 50%-drift reducing nozzles are required when a no-spray buffer zone of 15 m is respected
- a no-spray buffer zone of 20 m is respected

- Oilseed rape, maize, flax, hemp, soybean, sunflower, pumpkin, ornamentals < 50cm – 1 x 60 g a.s./ha:

- 50%-drift reducing nozzles are required when a no-spray buffer zone of 1 m is respected
- a no-spray buffer zone of 5 m is respected

Review Comments:

Based on available data for the LEPTOSAR 200 SL, can be concluded that any initial in-field effects on non-target arthropods from the proposed uses will be short-term and recolonisation will take place within an acceptable time frame.

The off-field risk for non-target arthropods from the applied uses of LEPTOSAR 200 SL is high for most of uses. Thus, safe use can be confirmed for those uses only when appropriate buffer zones will be introduced (see above).

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with acetamiprid and relevant metabolites. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of LEPTOSAR 200 SL were not evaluated as part of the EU assessment of acetamiprid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
~~*Eisenia fetida*~~	~~acetamiprid~~	~~14 d, acute~~	~~LC_{50} = 1.52 mg/kg dw~~[4]	~~Review Report, 2016~~
~~*Eisenia fetida*~~	~~Metabolite IM-1-2~~	~~14 d, acute~~	~~LC_{50} > 1000 mg/kg dw~~[2]	~~Review Report, 2016~~
~~*Eisenia fetida*~~	~~Metabolite IM-1-4~~	~~14 d, acute~~	~~LC_{50} > 1000 mg/kg dw~~[3]	~~Review Report, 2016~~
~~*Eisenia fetida*~~	~~Metabolite IC-0~~	~~14 d, acute~~	~~LC_{50} > 1000 mg/kg dw~~[4]	~~Review Report, 2016~~
~~*Eisenia fetida*~~	~~Metabolite IM-1-5~~	~~14 d, acute~~	~~LC_{50} > 1000 mg/kg dw~~[5]	~~Review Report, 2016~~
Eisenia fetida	Metabolite IM-1-5	Mixed into substrate 56 d, chronic	**NOEC= 62.5 mg/kg dw** EC_{10}/LC_{10} = > 62.5 mg/kg dw	EFSA Journal 2016;14(11):4610; Review Report, 2016
Folsomia candida	Metabolite IM-1-5	Mixed into substrate / 28 d, chronic	$NOEC_{mortality}$ = 62.7 mg/kg dw soil	EFSA Journal 2016;14(11):4610; Review Report, 2016

~~[4,2,3,4,5] Endpoints no longer required according to Regulation 283/2013. Nevertheless LC_{50} values are presented in dRR since according to RAR and EFSA conclusions on acetamiprid values for all soil metabolites are supportive information on their chronic toxicity to earthworms~~.

Species	Substance	Exposure System	Results	Reference
			$NOEC_{reproduction}$ = 12.5 mg/kg dw soil No EC values could be calculated as there were no effects below the highest tested value.	
~~*Eisenia fetida*~~	~~Representative formulation – Acetamiprid 20 SG~~	~~field study~~	~~Acetamiprid 20 SG at rates up to 80 g a.s./ha did not cause any adverse effects >50% on total earthworm abundance and biomass.~~	~~EFSA Journal 2016;14(11):4610; Review Report, 2016~~
~~*Folsomia candida*~~	~~Representative formulation – Acetamiprid 20 SG~~	~~Mixed into substrate 28 d, chronic 5% peat content~~	~~$NOEC_{mortality}$ = 0.49 mg a.s./kg soil d.w.~~ ~~LC_{10} = 0.82 mg a.s./kg soil d.w.~~ ~~**$NOEC_{reproduction}$ = 0.27 mg a.s./kg soil d.w.**~~ ~~EC_{10} = 0.47 mg a.s./kg soil d.w.~~	~~EFSA Journal 2016;14(11):4610; Review Report, 2016~~
~~*Hypoaspis aculeifer*~~	~~Representative formulation – Acetamiprid 20 SG~~	~~Mixed into substrate 14 d, chronic 5 % peat content~~	~~$NOEC_{mortality, reproduction}$ = 180 mg a.s./kg soil d.w.~~ ~~LC_{50} = > 180 mg a.s./kg soil d.w.~~ ~~**EC_{10} = 50.8 mg a.s./kg soil d.w.**~~	~~EFSA Journal 2016;14(11):4610; Review Report, 2016~~
Eisenia fetida	LEPTOSAR 200 SL	Mixed into substrate 56 d, chronic 10 % peat content	$LC_{50\ mortality}$ >3.08 mg a.s./kg soil d.w $NOEC_{mortality}$ = 1.71 mg a.s./kg soil d.w. $EC_{50,\ reproduction}$ > 3.08 mg a.s./kg soil d.w. $EC_{20,\ reproduction}$ =1.13 mg a.s./kg soil d.w. **$EC_{10,\ reproduction}$ = 0.49 mg a.s./kg soil d.w.** $NOEC_{reproduction}$ = 0.57 mg a.s./kg soil d.w.	Wołany, 2019a (Appendix 2)

Species	Substance	Exposure System	Results	Reference
Folsomia candida	LEPTOSAR 200 SL	Mixed into substrate 28 d, chronic 5 % peat content	$LC_{50,\ mortality}$ = 0.44 mg a.s./kg soil d.w. $LC_{20,\ mortlaity}$ = 0.27 mg a.s./kg soil d.w. $LC_{10,}$ mortality = 0.21 mg a.s./kg soil d.w. **NOEC $_{mortality,\ reproduction}$ = 0.17 mg a.s./kg soil d.w.** $EC_{50,\ reproduction}$ = 0.51 mg a.s./kg soil d.w. $EC_{20,\ reproduction}$ =0.27 mg a.s./kg soil d.w. $EC_{10,\ repduction}$ = 0.19 mg a.s./kg soil d.w.	Wołany, 2019b (Appendix 2)
Hypoaspis aculeifer	LEPTOSAR 200 SL	Mixed into substrate 14 d, chronic 5 % peat content	$LC_{50,\ mortality}$ > 3.08 mg a.s./kg soil d.w. $LC_{20,\ mortality}$ > 3.08 mg a.s./kg soil d.w. $LC_{10,\ mortality}$ > 3.08 mg a.s./kg soil d.w. NOEC $_{mortality} \geq$ 3.08 mg a.s./kg soil d.w. $EC_{50,\ reproduction}$ > 3.08 mg a.s./kg soil d.w. $EC_{20,\ reproduction}$ =1.25 mg a.s./kg soil d.w. $EC_{10,\ reproduction}$ = 0.57 mg a.s./kg soil d.w. **NOEC $_{reproduction}$ = 0.57 mg a.s./kg soil d.w.**	Wołany, 2019c (Appendix 2)
Field studies				
-				
Litter bag test				
-				

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002 (not needed for acetamiprid and its metabolites since their log Pow is below 2)

9.8.1.1 Justification for new endpoints

No deviation from EU agreed endpoints.

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for acetamiprid, metabolite IM-1-2 and IC-0, but it is relevant for metabolite IM-1-4 and IM-1-5.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for pumpkin with application of 1 × 60 g ai/ha covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses in groups (see 9.1.2).

Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of LEPTOSAR 200 SL in pumpkin

Intended use	**Pumpkin 1× 60 g ai/ha**		
~~**Acute effects on earthworms**~~			
~~**Product/active substance**~~	~~**LC_{50} (ai or metabolite mg/kg dw)**~~	~~**PEC_{soil}* (mg/kg dw)**~~	~~**TER_a (criterion TER ≥ 10)**~~
~~acetamiprid~~	~~1.52~~	~~0.0320~~	~~47.5~~
~~Metabolite IM-1-2~~	~~1000~~	~~0.0190~~	~~52632~~
~~Metabolite IM-1-4~~	~~1000~~	~~0.0171*~~	~~58480~~
~~Metabolite IC-0~~	~~1000~~	~~0.0026~~	~~93458~~
~~Metabolite IM-1-5~~	~~1000~~	~~0.0107*~~	~~384615~~
Chronic effects on earthworms			
Product/active substance	**EC10/NOEC (ai or metabolite mg/kg dw)**	**PEC_{soil}* (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Metabolite IM-1-5	62.5	0.0107	5841
LEPTOSAR 200 SL	0.49	0.0320	15
Chronic effects on other soil macro- and mesofauna			

Product/active substance	**NOEC (ai or metabolite mg/kg dw)**	**PEC_{soil}* (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Metabolite IM-1-5 *(Folsomia candida)*	12.5	0.0107	1168
~~Representative formulation Acetamiprid 20 SG *(Folsomia candida)*~~	~~0.27~~	~~0.0320~~	~~8~~
LEPTOSAR 200 SL *(Folsomia candida)*	0.17	0.0320	5.3
~~Representative formulation Acetamiprid 20 SG *(Hypoaspis aculeifer)*~~	~~50.8~~	~~0.0320~~	~~1588~~
LEPTOSAR 200 SL *(Hypoaspis aculeifer)*	0.57	0.0320	18

TER values shown in bold fall below the relevant trigger.
* In case of acetamiprid, metabolite IM-1-2 and IC-0 PEC initial values are used for the risk assessment. In case of IM-1-4 and IM-1-5 PECaccum. are stated since DT_{50} soil for these substances is above 100 d.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

The risk from exposure to acetamiprid and relevant soil degradation products applied as LEPTOSAR 200 SL for all intended uses is indicated to be acceptable for the soil meso- and macrofauna.

Review Comments:

The long-term risks of LEPTOSAR 200 SL to soil meso- and macro-organisms were assessed from toxicity exposure ratios between toxicity endpoints and maximum PEC_{soil}. The relevant predicted environmental concentrations in soil (PEC_{soil}) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate).

Safe use of LEPTOSAR 200 SL was confirmed based on TER_{LT} calculations for active substance' metabolite and for formulation.

9.8.4 Toxicity data

Studies on effects soil microorganisms have been carried out with representative formulation containing acetamiprid. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on soil microorganisms of LEPTOSAR 200 SL were not evaluated as part of the EU assessment of acetamiprid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.8-3: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
~~N-mineralisation~~	~~Representative formulation Acetamiprid 20 SG~~	~~28 d, aerobic~~	~~No negative effect > 25% at 28 d at 0.2 kg a.s./ha~~	~~EFSA Journal 2016;14(11):4610; Review Report, 2016~~
N-mineralisation	LEPTOSAR 200 SL	42 d, aerobic	No negative effect > 25% at 42 d at 0.16 mg a.s./kg dws	Wołany, 2019d (Appendix 2)

9.8.4.1 Justification for new endpoints

~~No deviation from EU agreed endpoints.~~ NA

9.8.5 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for pumpkin with application of 1 × 60 g ai/ha covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses in groups (see 9.1.2).

Table 9.8-4: Assessment of the risk for effects on soil micro-organisms due to the use of LEPTOSAR 200 SL in pumpkin

Intended use	**Pumpkin 1× 60 g ai/ha**		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**Application rate g ai/ha or PEC_{soil} (mg ai/kg dw)**	**Risk acceptable?**
~~Representative formulation Acetamiprid 20 SG~~	~~200 g ai /ha (at 28 d)~~	~~60 g ai/ha~~	~~yes~~
LEPTOSAR 200 SL	0.16 mg ai/kg dws (at 42 d)	0.0320 mg ai/kg dw	yes

9.8.6 Overall conclusions

The risk to soil microorganisms is acceptable since negligible effects on the nitrogen transformations are foreseen at higher levels than the calculated PEC soil values for the active when the intended use of pattern for the LEPTOSAR 200 SL is considered.

Review Comments:

LEPTOSAR 200 SL had no significant effect on soil micro-organisms at 0.16 mg a.s./kg dry soil. Based on it, can be concluded that LEPTOSAR 200 SL under field conditions, use at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

9.9 Effects on non-target terrestrial plants (KCP 10.6)

9.9.1 Toxicity data

~~Studies on the toxicity to non-target terrestrial plants have been carried out with acetamiprid based representative formulation. Full details of these studies are provided in the respective EU RAR and related documents.~~

Effects on non-target terrestrial plants of LEPTOSAR 200 SL were not evaluated as part of the EU assessment of acetamiprid. According to *Guidance Document on Terrestrial Ecotoxicology* SANCO/10329/2002 rev 2 final, 17 October 2002, only the screening data are required for plant protection products other than herbicides and plant growth regulators. Nevertheless new data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

~~The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.~~

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
~~Cucumber~~	~~Representative formulation Acetamiprid 20 SG~~	~~14 days Seedling emergence and vegetative vigour~~	~~1) ER_{50} emergence >500 g ai/ha 2) **ER_{50} vegetative vigour = 650 g ai/ha**[1]~~	~~EFSA Journal 2016;14(11):4610; Review Report, 2016~~
~~Cabbage, corn, lettuce, oat, onion, perennial ryegrass, soybean, tomato, turnip~~	~~Representative formulation Acetamiprid 20 SG~~	~~14 days Seedling emergence and vegetative vigour~~	~~1) ER_{50} emergence >500 g ai/ha 2) ER_{50} vegetative vigour = 700 g ai/ha~~	~~EFSA Journal 2016;14(11):4610; Review Report, 2016~~
Sunflower, d Cabbage, d Pea, d Carrot, d Perrenial reygrass, m Oat, m	LEPTOSAR 200 SL	14 d Seedling emergence	1) ER_{50} emergence > 60.5 g ai/ha 2) ER_{50} plant weight > 60.5 g ai/ha 3) ER_{50} plant height > 60.5 g ai/ha	Wołany, 2019e (Appendix 2)
Sunflower, d Cabbage, d Pea, d Carrot, d Perrenial reygrass, m Oat, m	LEPTOSAR 200 SL	21 d Vegetative vigour	) ER_{50} plant number > 60.5 g ai/ha 2) ER_{50} plant weight > 60.5 g ai/ha 3) ER_{50} plant height > 60.5 g ai/ha	Wołany, 2019f (Appendix 2)

m: monocotyledonous; d: dicotyledonous
[1] used in the risk assessment in RAR

9.9.1.1 Justification for new endpoints

No deviation from EU agreed endpoints.

9.9.2 Risk assessment

9.9.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

9.9.2.2 Tier-2 risk assessment (based on dose-response data)

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.
To achieve a concise risk assessment, he risk envelope approach is applied. Here, the assessment for the:

- field crops and vegetables < 50 cm height with application of 1 × 60 g ai/ha [5]
- vegetables > 50 cm height with application of 1 × 60 g ai/ha,[6]
- fruit crops (early stage) with application of 1 x 40 g a.s./ha ~~of 2 × 25 g ai/ha and 1 × 50 g ai/ha~~ [7]

covers the risk for non-target terrestrial plants from all intended uses in groups (see 9.1.8).

In case of indoor use of LEPTOSAR 200 SL (green house use) exposure to NTP is not relevant.

Table 9.9-2: Assessment of the risk for non-target plants due to the use of LEPTOSAR 200 SL in field crops

Intended use	Field crops			
Active substance/product	Acetamiprid/ LEPTOSAR 200 SL			
Application rate (g/ha)	1 × 60 g ai/ha			
MAF	1			
Test species	**ER_{50} (g ai/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
~~Cucumber~~	~~650~~	~~2.77%~~	~~1.662~~	~~391~~
Sunflower, d Cabbage, d Pea, d Carrot, d Perrenial reygrass, m Oat, m	60.5	2.77%	1.662	36.4
Intended use	Vegetables > 50 cm height			
Active substance/product	Acetamiprid/ LEPTOSAR 200 SL			
Application rate (g/ha)	1 × 60 g ai/ha			
MAF	1			

[5] Relevant for use in: oil seed rape, cereals, flax, hemp, poppy, sunflower and pumpkin
[6] Relevant for use in: soybean
[7] Relevant for use in: apple, pear, cherry, peach, nectarine, apricot, plum, tree nuts, common osier, purple willow, tobacco, forest nurseries/Christmas trees plantations

Test species	**ER_{50} (g ai/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
~~Cucumber~~	~~650~~	~~8.02%~~	~~4.812~~	~~135~~
Sunflower, d Cabbage, d Pea, d Carrot, d Perrenial reygrass, m Oat, m	60.5	8.02%	4.812	12.6
Intended use	Fruit crops early stage			
Active substance/product	Acetamiprid/ LEPTOSAR 200 SL			
Application rate (g/ha)	1 × 40 g ai/ha ~~and 2 × 25 g ai/ha~~			
MAF	1 ~~and 2~~			
Test species	**ER_{50} (g ai/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
~~Cucumber~~	~~650~~	~~29.20%~~	~~14.6~~	~~44.5~~
Sunflower, d Cabbage, d Pea, d Carrot, d Perrenial reygrass, m Oat, m	60.5	29.20%	~~14.6~~ 11.7	~~4.14~~ 5.2

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

9.9.2.3 Higher-tier risk assessment

Not relevant.

9.9.2.4 Risk mitigation measures

No risk mitigation needed for ~~almost~~ all intended uses ~~with exception of crops covered by scenario: fruit crops (early stage) with application of 2 × 25 g ai/ha and 1 × 50 g ai/ha~~[8]

~~In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no-spray buffer zones of 5 or 10 m; drift reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table.~~

~~**Table 9.9-3: Risk assessment for non-target terrestrial plants due to the use of LEPTOSAR 200 SL in fruit crops[4] considering risk mitigation (in-field no-spray buffer zones, and drift reducing nozzles)**~~

~~**Intended use**~~	~~Fruit crops early stage[4]~~
~~**Active substance/product**~~	~~Acetamiprid/ LEPTOSAR 200 SL~~
~~**Application rate (g/ha)**~~	~~1 × 50 g ai/ha and 2 × 25 g ai/ha~~

[4] Relevant for use in: apple, pear, cherry, peach, nectarine, apricot, plum, tree nuts, common osier, purple willow, tobacco, forest nurseries/Christmas trees plantations

MAF		1 and 2			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g/ha)**	**$PER_{off\text{-}field}$ 50 % drift red. (g/ha)**	**$PER_{off\text{-}field}$ 75 % drift red. (g/ha)**	**$PER_{off\text{-}field}$ 90 % drift red. (g/ha)**
3	29.20%	14.600	7.300	3.650	1.460
5	19.89%	9.945	4.973	2.486	0.995
10	11.81%	5.905	2.953	1.476	0.591
Toxicity value ER_{50} = 60.5 g a.i./ha		**TER criterion: TER ≥ 5**			
3		**4.14**	8.29	16.58	41.44
5		6.08	12.17	24.33	60.83
10		10.25	20.49	40.98	102.46

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

9.9.3 Overall conclusions

The table above shows that the TER for the almost all use patterns of LEPTOSAR 200 SL are above the trigger of 5 even when no risk mitigation measures are applied.

In case of use in minor uses such as: apple, pear, cherry, peach, nectarine, apricot, plum, tree nuts, common osier, purple willow, tobacco and forest nurseries/Christmas trees plantations an acceptable risk is indicated when the risk mitigation measure (either 50% drift reduction or a 5 m buffer strip) is applied.

Overall, the risk for non-target plants for LEPTOSAR 200 SL is acceptable.

Review Comments:

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002).

Based on the risk assessment it can be concluded that the proposed use of LEPTOSAR 200 SL poses no unacceptable risk to non-target plants, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from LEPTOSAR 200 SL applications are not required for the protection of terrestrial non-target plants.

9.10 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant.

9.11 Monitoring data (KCP 10.8)

No monitoring data are available and to be considered.

9.12 Classification and Labelling

According to REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006:
Ingredients classified as hazardous to the aquatic environment are:
- active substance acetamiprid in a concentration of 17 % classified as "Aquatic Chronic 3" according to agreed CLP Regulation.
-"Ingredient 3" being the mixture of components is in concentration of 0.01 %. Some of its components are classified as hazardous to the aquatic environment. However, according to point 4.1.3.1 of Regulation (EC) No 1272/2008 concerning the 'relevant components' "Ingredient 3" is not relevant component of a mixture. Therefore it is not taken into consideration in the classification of the product.

To see more details regarding confidential information please refer to Part C of dRR.

~~For classification of LEPTOSAR 200 SL summation method was used.~~

~~According to above information and Table 4.1.1 it was assumed that LEPTOSAR 200 SL is not classified as Acute Category 1 (none of its components is classified as "Aquatic Acute 1").~~

~~According to above information and Table 4.1.2 it was assumed that LEPTOSAR 200 SL is not classified as Chronic Category 3 (concentration of acetamiprid is equal 17 thus it is greater not than 25 %).~~

The lowest acute endpoint is an LC_{50} of 0.0104 mg f.p./L for the aquatic invertebrate species *Chironomus riparius*. Accordingly, a classification of Acute Aquatic 1 (H400: Very toxic to aquatic life) is proposed.

For chronic classification, no product data on LEPTOSAR 200 SL to the most sensitivity invertebrate species i.e. *Chironomus riparius* are available. Therefore, the chronic endpoint was derived based on the acute toxicity data according to the ECHA Guidance Document on the Application of the CLP Criteria (2017). Considering that the active substance is not readily biodegradable, as stated in the EFSA Conclusion on acetamiprid (2016), a classification of Chronic Aquatic 1 (H410: Very toxic to aquatic life with long lasting effects) is proposed.

Pictogram: GHS09
Signal Word: Warning
Hazard statement:
H410 – Very toxic to aquatic life with long lasting effects.

Precautionary statements:
P391 – Collect spillage.
P501 – Dispose of contents/container in accordance with applicable regulations

~~CLASSIFICATION~~	
~~Hazard class(es), categories:~~	~~none~~
~~LABELLING~~	
~~Hazard pictograms:~~	~~none~~
~~Signal word:~~	~~none~~
~~Hazard statement(s):~~	~~none~~

Precautionary statement(s):	none

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	Owner
KCP 10.2.1/01	Elżbieta Kulec-Płoszczyca	2019	A-200SL-OR3-C *Daphnia magna*, Acute immobilisation test W/01/19 Łukasiewicz Research Network –Institute Of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.2.1/02	Elżbieta Kulec-Płoszczyca	2019	A-200SL-OR3-C *Raphidocelis subcatitata* (*Pseudokirchinelaa subcatitata*), Growth inhibition test W/03/19 Łukasiewicz Research Network –Institute Of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.2.1/03	Paweł Bąk	2019	A-200SL-OR3-C *Chironomus sp*., Acute immobilisation test W/02/19 Łukasiewicz Research Network –Institute Of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.2.2/01	Katarzyna Brzozowska-Wojoczek	2019	A-200SL-OR3-C *Daphnia magna*, Reproduction test W/04/19 Łukasiewicz Research Network –Institute Of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.3.1/01	Mateusz Grzesica	2019	A-200SL-OR3-C Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test B/56/18 Łukasiewicz Research Network –Institute Of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.3.1/02	Mateusz Grzesica	2019	A-200SL-OR3-C Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test B/57/18 Łukasiewicz Research Network –Institute Of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.3.1/03	Mateusz Grzesica	2019	A-200SL-OR3-C Honeybees (*Apis mellifera* L.), Chronic Oral Toxicity Test B/13/19 Łukasiewicz Research Network –Institute Of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.3.1/04	Holewik Patrycja	2021	A-200SL-OR3-C Honeybees (*Apis mellifera* L.), Larval Toxicity Test, Repeated Exposure B/56/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.3.2/01	Paweł Parma	2019	An extended laboratory test for evaluating the effects of A-200SL-OR3-C on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani - Perez) B/09/19 Łukasiewicz Research Network –Institute Of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.3.2/02	Monika Stalmach	2019	An extended laboratory test for evaluating the effects of A-200SL-OR3-C on the predatory mite, *Typhlodromus pyri* (Sch.) B/10/19 Łukasiewicz Research Network –Institute Of Industrial Organic Chemistry Branch Pszczyna	N	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCP 10.3.2/03	Monika Stalmach	2019	An extended laboratory test for evaluating the effects of A-200SL-OR3-C on the green lacewings, *Chrysoperla carnea* (Steph.) B/11/19 Łukasiewicz Research Network –Institute Of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.3.2/04	Monika Stalmach	2019	An extended laboratory test for evaluating the effects of A-200SL-OR3-C on the ladybird beetle, *Coccinella septempunctata* L. B/12/19 Łukasiewicz Research Network –Institute Of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.3.2/05	James Stevens	2019	A-200SL-OR3-C – Aged-residue extended laboratory tests to determine effects on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera, Braconidae) Report No. CIE-19-11 Mambo-Tox A Division of Cawood Scientific Ltd. GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.3.2/06	Lisa Fallowfield	2019	A-200SL-OR3-C – Aged-residue extended laboratory tests to determine effects on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae) Report No. CIE-19-10 Mambo-Tox A Division of Cawood Scientific Ltd. GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.3.2/07	Russell Vaughan	2019	A-200SL-OR3-C – A series of aged-residue extended laboratory tests to determine effects on the green lacewing, *Chrysoperla carnea* (Neuroptera, Chrysopidae)	N	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.3.2/08	Russell Vaughan	2019	A-200SL-OR3-C – A series of aged-residue extended laboratory test to determine effects on the ladybird beetle, *Coccinella septempunctata* (Coleoptera: Coccinellidae). Report No. CIE-19-12 Mambo-Tox A Division of Cawood Scientific Ltd. GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.4.1	Wołany M.	2019a	Report A-200SL-OR3-C: Earthworm Reproduction Test (*Eisenia andrei*) according to the OECD Guideline No. 222 (2016) STUDY CODE: G/147/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.4.2/01	Wołany M.	2019b	Report A-200SL-OR3-C: Collembolan *(Folsomia candida)* Reproduction Test according to OECD Guideline No. 232 (2016) STUDY CODE: G/148/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.4.2/02	Wołany M.	2019c	Report A-200SL-OR3-C: Predatory mite (*Hypoaspis* (*Geolaelaps*) *aculeifer*) reproduction test in soil according to the OECD Guideline No. 226 (2016) STUDY CODE:G/149/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.5	Wołany M.	2019d	Report A-200SL-OR3-C: Soil Microorganisms: Nitrogen Transformation Test according to the OECD Guideline No. 216 (2000)/EU Method C.21 STUDY CODE: G/150/18 Institute of Industrial Organic Chemistry Branch Pszczyna	N	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCP 10.6/01	Wołany M.	2019e	Report A-200SL-OR3-C: Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test according to the OECD Guideline No. 208 (2006) STUDY CODE: G/152/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.6/02	Wołany M.	2019f	Report A-200SL-OR3-C: Terrestrial Plant Test: Vegetative Vigour Test according to the OECD Guideline No. 227 (2006) STUDY CODE: G/151/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	CIECH Sarzyna S.A.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

A 2.2 KCP 10.2 Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Study 1

Comments of zRMS:	The study was conducted to OECD guideline 202 and according to the principles of GLP. No deviations to the guideline were noted.

Reference:	KCP 10.2.1/01
Report	A-200SL-OR3-C, *Daphnia magna*, Acute Immobilization Test, Elżbieta Kulec-Płoszczyca, MSc, STUDY CODE: W/01/19, Łukasiewicz Research Network –Institute of Industrial Organic Chemistry Branch Pszczyna Department of Ecotoxicology, Poland
Guideline(s):	Yes. According to the OECD Guideline No. 202 (2004)
Deviations:	No
GLP:	Yes

Acceptability: Yes

Materials and methods

Test item: name: A-200SL-OR3-C; active ingredients content (analysed): acetamiprid: 201.7 g/L, batch number: 3/18; manufacturing date: 11.2018; expiry date: 11.2020

Test organism: The test organism, i.e. *Daphnia magna* Straus originated from a standard laboratory culture cultivated at ŁUKASIEWICZ RESEARCH NETWORK – INSTITUTE OF INDUSTRIAL ORGANIC CHEMISTRY, BRANCH PSZCZYNA, Department of Ecotoxicology, Laboratory of Aquatic Toxicology
[SOP/W/67]. Only organisms aged less than 24 h (not first brood progeny) were used in the tests. The sensitivity of the culture was monitored on a regular basis using a reference material, potassium dichromate [SOP/W/72].

Test design: 4 replicates per test item concentration and the control; 5 Daphnia magna in each replicate.

Test conditions:

- temperature: 19.9 – 21.6°C
- controlled light – dark cycles (16h : 8h)
- ph of the control: 7.33 – 7.41
- dissolved oxygen concentration in the control: 9.2 – 9.8 mg/L

Tested concentrations: 100 mg/L plus the control (limit test)

Test type: static

Study duration: 48 h

Endpoints: EC_{50}

The aim of the study was to demonstrate that the test item concentration causing 50% immobilisation of *Daphnia magna* (the EC50 value after 48 h of exposure) is higher than the test item concentration used for exposure i.e. 100 mg/L (limit test).

Results and discussions

In the control and in the test item concentration of 100 mg/l no immobilization was observed during exposure. The endpoints were determined on the basis of nominal test item concentration. In the test item concentration of 100 mg/l and in the control no immobilization of Daphnia magna was observed during

exposure. Since the immobilization of Daphnia magna was less than 10%, no statistical analysis was needed. The EC_{50}/48 h value based on nominal test item concentration is higher than 100 mg/L.

At exposure initiation the determined concentration of acetamiprid was 97.2%. The results confirm that the test item concentration was prepared correctly. At exposure termination the determined concentration of acetamiprid was 96.0% of the nominal concentration. Therefore, acetamiprid concentration was stable under test conditions.

Validity criteria:
The results are considered valid because the following criteria were met according to OECD Guideline No. 202 (2004):
- the percentage of immobilisation of Daphnia magna in the control was 0% (criterion: not more than 10%),
- the dissolved oxygen concentrations in the test vessels were within the range of 9.2 – 9.8 mg/L (criterion: not less than 3 mg/L).

Conclusion

The endpoint values based on nominal test item concentration is given below:
The EC50/48 h is higher than 100 mg/L

Study 2

Comments of zRMS:	The study was conducted to OECD guideline 201 and according to the principles of GLP. No deviations to the guideline were noted.

Reference:	KCP 10.2.1/02
Report	A-200SL-OR3-C, *Raphidocelis subcapitata* SAG 61.81 (*formerly Pseudokirchneriella subcapitata*) Growth inhibition test, Elżbieta Kulec-Płoszczyca, MSc, STUDY CODE: W/03/19, Łukasiewicz Research Network –Institute of Industrial Organic Chemistry Branch Pszczyna Department of Ecotoxicology, Poland
Guideline(s):	Yes. According to the OECD Guideline No. 201 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test item:	name: A-200SL-OR3-C; active ingredients content (analysed): acetamiprid: 201.7 g/L, batch number: 3/18; manufacturing date: 11.2018; expiry date: 11.2020

Test organism:	The unicellular freshwater green algae, Raphidocelis subcapitata SAG 61.81 (formerly Pseudokirchneriella subcapitata (Reinsch) Korshikov (syn. Selenastrum capricornutum Prinz) cultivated at the ŁUKASIEWICZ RESEARCH NETWORK – INSTITUTE OF INDUSTRIAL ORGANIC CHEMISTRY, BRANCH PSZCZYNA, Department of Ecotoxicology, Laboratory of Aquatic Toxicology. The algae were obtained from the Culture Collection of Algae at Göttingen University, Germany.
Test design:	six replicates for the test item concentration and six for the control; a background for the control and the test item concentration; initial algal cell density: 1 x 10^4 cells/mL.
Test conditions:	- temperature: 21.5 – 22.8ºC - light intensity and quality: 7218 – 7628 lux - ph of the control: 7.57 – 7.51
Tested concentrations:	100 mg/L plus the control.
Test type:	shake culture
Study duration:	72 h
Endpoints:	ErC_{50}, EyC_{50}

The aim of the study was to demonstrate that the test item concentration causing 50% inhibition of growth rate and yield of the algae, Raphidocelis subcapitata SAG 61.81 (formerly Pseudokirchneriella subcapitata) (ErC50 and EyC50 after 72 hours of exposure, respectively) are higher than the test item concentration used for exposure i.e. 100 mg/L (limit test).

Results and discussions

The endpoint values were determined on the basis of the nominal test item concentrations. The E_rC_x and the E_yC_x values were calculated with the probit method. To conduct ststistical analyses, the ToxRat Professional commercial software was used. Results are shown in Tables below.
In all test item concentrations no differences of algae cells were reported as compared to the algae cells in the control.

At exposure initiation, the determined concentration of acetamiprid was 97.4% of the nominal concentration. The results confirm that the test item concentration was prepared correctly. At exposure termination the determined concentration of acetamiprid was 98.0% of the nominal concentration. Therefore, the concentrations of acetamiprid was stable under test conditions.

Statistical tests based on the growth rate data were Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) showed that the variances were homogeneous and Two sample Welch-t-test Procedure which did not

show significant difference between the nominal test item concentration of 100 mg/L and the control. The concentration causing a 50% inhibition of yield of Raphidocelis subcapitata, i.e. the EyC50/72 h value is higher than 100 mg/L. Statistical tests based on the yield data were Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) showed that the variances were homogeneous and Two-sample -t-test Procedure which did not show significant difference between the nominal test item concentration 100 mg/L and the control.

Table 1. Growth rate endpoint values based on the nominal test item concentrations, definitive test

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
E_rC_{50}	> 100	> 100	> 100

Table 2. Yield endpoint values based on the nominal test item concentrations, definitive test

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
E_yC_{50}	> 100	> 100	> 100

Validity criteria:
The results are considered valid because the following criteria were met according to OECD Guideline No. 201 (2006):
- the biomass in the control increased by a factor of 172.6 within the 72-hour test period (criterion: at least a 16-fold growth),
- the coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation – exposure termination) in the control culture was 2.0% (criterion: it must not exceed 7%),
- the mean coefficient of variation for the section-by-section growth rate in the control culture was 10.3% (criterion: it must not exceed 35%).

Conclusion

The concentration causing a 50% inhibition of the growth rate of Raphidocelis subcapitata, i.e. the ErC50/72 h value is higher than 100 mg/L.
The concentration causing a 50% inhibition of yield of Raphidocelis subcapitata, i.e. the EyC50/72 h value is higher than 100 mg/L.

Study 3

Comments of zRMS:	The study was conducted to OECD guideline 235 and according to the principles of GLP. No deviations to the guideline were noted.

Reference: KCP 10.2.1/03

Report A-200SL-OR3-C, *Chironomus sp.*, Acute immobilisation test, Paweł Bąk,

	MSc, STUDY CODE: W/02/19, Łukasiewicz Research Network –Institute of Industrial Organic Chemistry Branch Pszczyna Department of Ecotoxicology, Poland
Guideline(s):	Yes. According to the OECD Guideline No. 235 (2011)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test item:	name: A-200SL-OR3-C; active ingredients content (analysed): acetamiprid: 201.7 g/L, batch number: 3/18; manufacturing date: 11.2018; expiry date: 11.2020
Test organism:	First instar larvae of the freshwater dipteran midge *Chironomus riparius* Meigen 1804 (two-four days after hatching); collected from a laboratory culture cultivated at the ŁUKASIEWICZ RESEARCH NETWORK – INSTITUTE OF INDUSTRIAL ORGANIC CHEMISTRY, BRANCH PSZCZYNA, Department of Ecotoxicology, Laboratory of Aquatic Toxicology.
Test design:	4 replicates per each test item concentration and the control; 5 larvaes in each replicate
Test conditions:	- temperature: 20.3 – 20.9°C - controlled light – dark cycles (16h : 8h) - ph of the control: 7.07 – 7.23 - dissolved oxygen concentration: 8.6 – 9.2 mg/L
Tested concentrations:	0.1, 0.05, 0.025, 0.013, 0.0063, 0.0031 mg/L plus the control
Test type:	static
Study duration:	48 h
Endpoints:	EC_{50}, NOEC and LOEC.

The aim of the study was to determine the test item concentration causing 50% immobilisation of *Chironomus riparius*, i.e. the EC50 value after 48 hours of exposure. The LOEC and the NOEC values were also determined.

Results and discussions

The determined concentrations of acetamiprid were in the range of 89.7 – 116.7% of nominal concentration. Therefore, the results confirm correct preparation of the test item concentrations. In samples collected at exposure termination, in the test item concentrations in the range of 0.0063 – 0.1 mg/L, the determined test item concentrations were in the range of 95.3 – 109.9% of nominal concentration. Therefore, the test item concentrations were stable under test conditions.

The endpoint values were determined on the basis of the nominal test item concentrations. The ECx values were calculated with the probit method [SOP/W/68]. The lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) were estimated on the basis of statistical analyses [SOP/W/68]. To make calculations and to conduct statistical analyses, the ToxRat Professional commercial software was used. The endpoint values are presented in Table 1.

Table 1. Endpoint values based on the nominal test item concentrations, definitive test

Endpoint values [mg/L]	Time of exposure	
	24 h	48 h
EC_{50}	0.0267 (0.0192 – 0.0389)	0.0104 (0.0073 – 0.0141)
EC_{20}	0.0093 (0.0053 – 0.0134)	0.0041 (0.0022 – 0.0060)
EC_{10}	0.0054 (0.0024 – 0.0084)	< 0.0031
LOEC	0.025	0.0063
NOEC	0.013	0.0031

Calculations were made according to [4], [SOP/W/68]
(-) - 95% confidence limits

Validity criteria:

The results are considered valid because the following criteria were met according to OECD Guideline No. 235 (2011):
- the immobilisation of *Chironomus riparius* larvaes in the control was 5% (criterion: not more than 15%),
- the dissolved oxygen concentrations in the test vessels were within the range of 8.6 – 9.2 mg/L (criterion: not less than 3 mg/L).

Conclusion

The endpoint values determined on the basis of the nominal test item concentrations are given below:
The EC50/48 h value is 0.0104 mg/L (95% confidence limits: 0.0073 – 0.0141)
The LOEC/48 h value is 0.0063 mg/L. The NOEC/48 h value is 0.0031 mg/L.

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

Study 1

Comments of zRMS:	The study was conducted to OECD guideline 211 and according to the principles of GLP. No deviations to the guideline were noted.

Reference:	KCP 10.2.2/01
Report	A-200SL-OR3-C, *Daphnia magna*, Reproduction test, Katarzyna Brzozowska-Wojoczek, STUDY CODE: W/04/19, Łukasiewicz Research Network –Institute of Industrial Organic Chemistry Branch Pszczyna Department of Ecotoxicology, Poland
Guideline(s):	Yes. According to the OECD Guideline No. 211 (2012)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test item: name: A-200SL-OR3-C; active ingredients content (analysed): acetamiprid: 201.7 g/L, batch number: 3/18; manufacturing date: 11.2018; expiry date: 11.2020

Test organism: Daphnia magna Straus (< 24 h old at the exposure initiation); not first brood progeny; range of parent Daphnia magna age: 21 – 25 days (22 days old); test organisms collected from the laboratory culture cultivated at the ŁUKASIEWICZ RESEARCH NETWORK – INSTITUTE OF INDUSTRIAL ORGANIC CHEMISTRY, BRANCH PSZCZYNA, Department of Ecotoxicology, Laboratory of Aquatic Toxicology.

Test design: 10 replicates per test item concentration and the control with one parent *Daphnia magna* held individually

Test conditions:

- temperature: 18.8 – 21.0 ºC
- controlled light – dark cycles (16h : 8h)
- ph of the control: 7.08– 7.69
- dissolved oxygen concentration in the control: 8.2 – 8.9 mg/L

Tested concentrations: 10 mg/L plus the control

Test type: Semi-static

Study duration: 21 days

Endpoints: ECx, based on the number of living offspring produced per introduced and survived parent Daphnia magna at exposure termination, immobilisation of parent Daphnia magna, the final body size (body length) of parent Daphnia magna and the intrinsic rate of population growth

The aim of the study was to demonstrate that there is no statistically significant effect on reproductive output, mortality and growth, i.e. body length of parent Daphnia magna between the test item concentration of 10 mg/L and the control, and to demonstrate that the test item concentration causing 50% reduction (EC50 value after 21 days of exposure) is higher than the test item concentration used.

Results and discussions

The concentrations of acetamiprid were chemically determined using a validated liquid chromatographic method. The concentrations of acetamiprid determined in fresh samples collected at exposure initiation, on days: 7, 14 and 19 of exposure were in the ranges of 96.9 – 104.0% of nominal concentration. The concentrations of acetamiprid determined in spent samples collected on days: 3, 10, 17 and 21 of exposure were in the ranges of 97.2 – 103.5% of nominal concentrations. The chemical determinations confirmed stability of the concentrations of acetamiprid in periods between renewals in a semi-static test.

The results obtained in the study made it possible to calculate EC_{10}/21d, EC_{20}/21d, EC_{50}/21d and NOEC, LOEC values. The values of effective concentrations and LOEC/NOEC were obtained using ToxRat Professional statistical program.

Validity criteria:
The results are considered valid because the following criteria were met according to OECD Guideline No. 211
- the mortality of the parent Daphnia magna (defined as immobilisation together with accidental and/or inadvertent immobilisation) in the control was 10% and hence did not exceed 20% at exposure termination.
- the mean number of living offspring produced per parent Daphnia magna surviving at exposure termination (defined as the number of living offspring produced per parent Daphnia magna alive at exposure termination, i.e. the mean cumulative number of offspring per survivor) in the control was 129.6 (criterium, higher than 60).

Conclusion

In Daphnia magna reproduction semi-static test, the endpoint values were determined based on the nominal test item concentration.
Number of living offspring produced per survived parent Daphnia magna at exposure termination (i.e. the mean cumulative number of offspring per survivor):
EC10/21 d, EC20/21 d and EC50/21 d values are higher than 10 mg/L.
The NOEC value is higher than or equal to 10 mg/L.

Immobilisation of parent *Daphnia magna*:
EC10/21 d, EC20/21 d and EC50/21 d values are higher than 10 mg/L.
The NOEC value is higher than or equal to 10 mg/L.

Final body size (body length) of parent *Daphnia magna*:
EC10/21 d, EC20/21 d and EC50/21 d values are higher than 10 mg/L.
The NOEC value is higher than or equal to 10 mg/L.

Intrinsic rate of population growth:
EC10/21 d, EC20/21 d and EC50/21 d values are higher than 10 mg/L.
The NOEC value is higher than or equal to 10 mg/L.

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

A 2.3.1.1.1.1 Study 1

Comments of zRMS:	The study was conducted to OECD guideline 213 and according to the principles of GLP. No deviations to the guideline were noted.

Reference:	KCP 10.3.1
Report	A-200SL-OR3-C Honeybees (*Apis mellifera L.*), Acute Oral Toxicity Test, M. Grzesica, 2019, B/56/18, Institute Of Industrial Organic Chemistry Branch, Pszczyna
Guideline(s):	Yes (OECD Guideline for the Testing of Chemicals No. 213 (1998): "Honeybees, Acute Oral Toxicity Test")
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Materials and methods

Test item:	name: A-200SL-OR3-C, active substance: 201,7 g/L of acetamipryd batch number: 3/18

	manufacturing date: 29.11.2018 expiry date: 28.11.2020
Biological test system:	the honeybee, *Apis mellifera* L., strain: carnica source: an apiary at the Institute Of Industrial Organic Chemistry, Branch Pszczyna, age: approximately 3 weeks
Test conditions:	temperature: 24 – 26ºC, relative air humidity: 58 – 67% place: a dark room

The acute oral toxicity study of A-200SL-OR3-C described in this report was conducted to determine the LD_{50} values for honeybees. Four doses of the test item were used. These included: 4.7, 10.3, 22.7 and 50.0 µg/honeybee. The range of the doses was selected on the basis of the preliminary test results.
Each group of 10 bees (3 replicates containing 10 bees each) was fed with 100 µL of a 50% sucrose solution, containing the test item at the doses mentioned above, using a micropipette. During the entire experiment, the insects were caged in groups of 10.
The general condition of the test honeybees and the reliability of the tests conducted on them were controlled using the recommended reference item – dimethoate.
After the administration, the insects were observed for mortality and other signs of toxicity. These observations were made 4 hours after the beginning of the treatment and then every 24 hours after the beginning of the treatment. The acute oral toxicity test ended after the 48-hour exposure.

Results and discussions

The acute oral toxicity study of the test item, A-200SL-OR3-C on honeybees (*Apis mellifera* L.) in the laboratory test are summarized below.

Dose [µg/bee]	Number of tested bees [no.]	Mortality after 48 h		LD_{50} after 48 h [µg/bee]
		Total		
		[no.]	[%]	
0.0 (Control)	30	0	**0.0**	**25.53**
4.7	30	0	**0.0**	
10.3	30	3	**10.0**	
22.7	30	6	**20.0**	
50.0	30	30	**100.0**	

After 48 hours of exposure, mortality of the control group was 0.0% and for the treated groups' mortality percentages at the doses 4.7, 10.3, 22.7 and 50.0 µg/bee, were 0.0, 10.0, 20.0 and 100.0%,
respectively. The median lethal doses (LD_{50} oral) after 24 and 48 hours of exposure are 27.51 and 25.53 µg test item /bee.
The following validity criteria were met during the test:
- the average mortality for the total number of controls was 0.0% at the end of the experiment (criterion: it must not exceed 10%).
- the LD_{50}/24 h of the reference item (dimethoate) was 0.27 µg a.i./bee (criterion: 0.10 – 0.35 µg a.i./bee).

Conclusions:

The median lethal doses (LD_{50} oral) after 24 and 48 hours of exposure are 27.51 µg test item /bee

(47.1 µg a.i./bee) and 25.53 µg test item /bee (43.8 µg a.i./bee).

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	The study was conducted to OECD guideline 214 and according to the principles of GLP. No deviations to the guideline were noted.

Reference:	KCP 10.3.1
Report	A-200SL-OR3-C Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test, M. Grzesica, 2019, B/57/18, Institute Of Industrial Organic Chemistry Branch, Pszczyna
Guideline(s):	Yes (OECD Guideline for the Testing of Chemicals No. 214 (1998) and the EU Method C.17. (2008))
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test item:	name: A-200SL-OR3-C, active substance: 201,7 g/L of acetamipryd batch number: 3/18 manufacturing date: 29.11.2018 expiry date: 28.11.2020
Biological test system:	the honeybee, *Apis mellifera* L., strain: carnica source: an apiary at the Institute Of Industrial Organic Chemistry, Branch Pszczyna, age: approximately 3 weeks
Test conditions:	temperature: 24 – 26ºC, relative air humidity: 58 – 68% place: a dark room

The acute contact toxicity study of A-200SL-OR3-C was conducted to determine the LD_{50}. Four doses of the test item were used. These included: 4.7, 10.3, 22.7 and 50.0 µg/honeybee. The range of doses was selected on the basis of the preliminary test results.
A microapplicator was used to apply the test item. The volume was 1 µL/bee. During the experiment, the insects were caged in groups of 10.
The recommended reference item, i.e. dimethoate was used to verify the sensitivity of the honeybees and the precision of the test procedure.
After the application, the insects were observed for mortality and signs of toxicity. These observations were made 4, 24, and 48 hours after the beginning of the treatment. The acute contact toxicity test finished after the 48-hour observation.

Mortality of the control group after 48 hours of exposure was 10.0%. The percentages of mortality of the bees treated with the test item at the doses of 8.0, 40.0 and 200.0 µg/honeybee were 22.2, 44.4 and 100.0%, respectively. No abnormal behavioural effects were observed during the test.

The following validity criteria were met during the test:
- the average mortality for the total number of controls was 3.3% after 48 h (criterion: it must not exceed 10%),
- the LD_{50}/24 h of the reference item (dimethoate) was 0.24 µg a.i./bee (criterion: 0.10 – 0.30 µg a.i./bee).

Results:

The acute contact toxicity study of the test item, A-200SL-OR3-C on honeybees (*Apis mellifera* L.) in the laboratory test are summarized below.

Dose [µg/bee]	Number of tested bees [no.]	Mortality after 48 h after the beginning of the treatment			LD_{50} [µg/bee]
		Total			
		[no.]	[%]	[%][c]	
0.0 (Control)	30	1	**3.3**	–	**>50.0**
4.7	30	0	**0.0**	**0.0**	
10.3	30	1	**3.3**	**0.0**	
22.7	30	2	**6.7**	**3.4**	
50.0	30	1	**3.3**	**0.0**	

Conclusions:

The median lethal doses (LD_{50}/24 h and LD_{50}/48 h contact) are higher than the highest dose used in the test, i.e. 50.0 µg/honeybee (85.7µg a.i./bee).

A 2.3.1.2 KCP 10.3.1.2 Chronic toxicity to bees

Comments of zRMS:	The study was conducted to OECD guideline 245 and according to the principles of GLP. No deviations to the guideline were noted.
Reference:	KCP 10.3.1
Report	A-200SL-OR3-C, Honeybees (*Apis mellifera* L.), Chronic Oral Toxicity Test, M. Grzesica, 2019, B/13/19, Institute Of Industrial Organic Chemistry Branch, Pszczyna
Guideline(s):	Yes (according to the OECD Guideline for the Testing of Chemicals No. 245 (2017))
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test item:	name: A-200SL-OR3-C, active substance: 201,7 g/L of acetamipryd batch number: 3/18 manufacturing date: 29.11.2018 expiry date: 28.11.2020
Biological test system:	species: the honeybee, *Apis mellifera* L.; strain: carnica, source: an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; age: freshly emerged worker honeybees from the same queen-right colony
Test conditions:	temperature: 33 – 34ºC; relative humidity: 56 – 68%

The mortality of honeybees exposed to A-200SL-OR3-C was investigated during 10-days chronic oral toxicity test.
Five doses of the test item was used. The concentrations were 21, 42, 84, 167, 333 mg/kg of diet (corresponding to the nominal doses of: 0.625, 1.25, 2.5. 5.0, 10.0 µg/honeybees/day, respectively).
Daily doses, consumed by the bees in the groups treated with the test item at the concentrations of 21, 42, 84, 167, 333 mg/kg were 0.6, 1.2, 2.1, 4.1, 9.6 µg/bee/day. Daily doses were calculated on the basis of average consumption of a treated 50% sucrose solution in each study groups and the nominal dose given to the bees.

Each group of bees (3 replicates/group; 10 bees/replicate) was fed with 2 mL of a 50% sucrose solution containing the test item at the concentrations of 21, 42, 84, 167, 333 mg/kg, or 50% sucrose solution alone (control group) for 10 days. The group treated with the reference item (3 replicates per 10 bees) was fed the with 2 mL of a 50% sucrose solution containing reference item at the concentration of 0.75 mg/kg. Daily weighed feeders were used. During the experiment, the insects were caged in groups of 10.
Dimethoate, which is a recommended reference item, was used to verify the sensitivity of the bees and the precision of the test procedure.

The insects were observed for mortality and behavioural abnormalities (signs of intoxication) at daily intervals up to 10 days of exposure.
Average consumption of a 50% sucrose solution in the control group was 24.44 mg/bee/day. Average consumption in the groups treated with the test item at the concentrations of 21, 42, 84, 167, 333 mg/kg were 29.97, 29.82, 25.08, 24.53, 28.73 mg/bee/day, respectively. Average consumption of a 50% sucrose solution containing the reference item at the concentration of 0.75 mg/kg was 23.20 mg/bee/day.

The concentrations of the acetamipryd were chemically determined with a validated liqiud chromatographic method with DAD detection. Samples of the highest and the lowest test item concentrations (of 333 and 21 mg/kg) and and the control were chemically analyzed at test initiation and at the end of the maximum storage period (i.e. after 4 days). At exposure initiation, in the fresh samples of the test item of 21 and 333 mg/kg, the concentrations of acetamiprid were 98.8 and 96.4%, respectively. The results confirm that the test item solutions were prepared correctly.
After 4 days of the storage period, in the samples of the test item of 21 and 333 mg/kg, the concentrations of acetamipryd were 99.0 and 97.0%, respectively. Based on the results of chemical analyses, the concentrations of acetamiprid were stable under storage conditions.

The effects of A-200SL-OR3-C on mortality of honey bees are summarized below:

Nominal test item dose [µg/bee/day]	Nominal test item concentration [mg/kg]	Consumed [a] dose [µg/bee/day]	Number of tested bees [no]	Total mortality			LDD_{50} [µg/bee/day]	LC_{50} [mg/kg]
				No.	[%]	Corr. [%][b]		
A-200SL-OR3-C								
0.0 (Control)			30	4	13.3	–	> 9.6	> 333
0.625	21	0.6	30	1	3.3	-11.5		
1.25	42	1.2	30	0	0.0	-15.4		
2.5	84	2.1	30	0	0.0	-15.4		
5.0	167	4.1	30	3	10.0	-3.9		
10.0	333 [+]	9.6	30	7	23.3	11.5		
NOEDD [µg/bee/day]			≥ 9.6					
NOEC [mg/kg]			167					
Dimethoate (reference item)								
0.0225	0.75	0.017	30	27	90.0	88.5	Not determined	

[a]: ingested doses (dietary doses) were calculated on the basis of the concentrations of the test item / reference item and average sucrose solution consumption
[b]: mortality corrected to the formula af Abbott [8]
[+]: statistically significant difference [7] [SOP/B/67]

Results:

The validity criterion concerning mortality was met, because mortality in the control was 13.3% after 10 days of exposure.
The percentages of mortality, corrected using Abbott's formula, of the honeybees exposed to the test item, A-200SL-OR3-C at the concentrations of 21, 42, 84, 167, 333, mg/kg (dietary doses: 0.6, 1.2, 2.1, 4.1, 9.6 µgbee/day) at the end of exposure (day 10) were (-11.5), (-15.4), (-15.4), (-3.9) and 11.5%. The negative values indicate that mortality in the treated groups were lower than in the control group.
On the basis of the obtained mortality results the LC50 is higher than 333 mg/kg, and the LDD_{50} value is higher than 9.6 µg/bee/day. The NOEC value is 167 mg/kg, while the NOEDD is higher than of equal to 9.6 µg/bee/day.
The validity criterion concerning mortality of the honeybees exposed to the reference item, dimethoate was met, because corrected mortality was equal to 88.5% after 10 days of exposure. The results obtained in the reference item group showed that the insects were sensitive to dimethoate.

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Comments of zRMS:	The study was conducted to OECD guideline 239 and according to the principles of GLP. No deviations to the guideline were noted.

Reference: KCP 10.3.1 /04

Report	A-200SL-OR3-C Honeybees (Apis mellifera L.), Larval Toxicity Test, Repeated Exposure, P.Holewik, B-56-21
Guideline(s):	OECD Guidance document 239 (2016)
Deviations:	None
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

MATERIALS AND METHODS

The study was performed according to the OECD Guidance Document for Testing Chemicals No. 239 (2016): 'Honeybees (Apis mellifera L.), larval toxicity test, repeated exposure'

Test item

Name:	A-200SL-OR3-C
Batch number:	1/2021
Production date:	03.02.2021
Expiry date:	03.02.2023
Appearance:	clear liquid
Active substance:	200.3 g/L of acetamiprid

Biological test system

species: the honeybee, *Apis mellifera* L.; strain: carnica

source: an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna

age: one-day-old larvae, first instar (L1)

Larvae were taken from three healthy, queen-right families (3 replicates) with known history and physiological status. Families had not been treated with chemical substances, such as antibiotics, anti-varroa, etc. for four weeks before the experiment.

In the preliminary test, three doses, i.e. 1.0, 10.0, and 100.0 µg/larva and control group were used. There were two replicates of each dose (12 larvae/replicate).

In the definitive test, five doses, in a geometric series, spaced by a factor of 3, i.e. 1.1, 3.3, 10.0, 30.0 and 90.0 µg/larva, plus the control and one dose of a reference item were used. There were three replicates of each dose (3 replicates/dose; 12 larvae/replicate).

The larvae were fed with diet B or C treated with the test item or reference item, from day 3 to 6 of the experiment.

The food was composed of the three following diets, adapted to the needs of the larvae at different stages of development:

Diet A (D1) in the volume of 20 µL per one larva: 50% weight of fresh royal jelly + 50% weight of an aqueous solution containing 2% weight of yeast extract, 12% weight of glucose and 12% weight of fructose.

Diet B (D3) in the volume of 30 µL per one larva: 50% weight of fresh royal jelly + 50% weight of an aqueous solution containing 3% weight of yeast extract, 15% weight of glucose and 15% weight of fructose.

Diet C (D4 in the volume of 30 µL per one larva, D5: 40 µL/ larva, D6 :50 µL/ larva): 50% weight of fresh royal jelly + 50% weight of an aqueous solution containing 4% weight of yeast extract, 18% weight of glucose and 18% weight of fructose.

The fresh diet was prepared on each feeding day.

RESULTS AND CONCLUSION:

Mortality of the control group on day 8 (D8) of the test was 2.8% (criterion: ≤ 15%). The percentages of corrected mortality of the honeybee larvae, exposed to the test item, at the doses of 1.1, 3.3, 10.0, 30.0 and 90.0 µg/larva at D8 were: 14.3, 25.7, 71.4, 74.3 and 85.7%, respectively. The percentage of larval corrected mortality on D8 in the reference item group was 94.3%.

Pupal mortality of the control group on day 15 (D15) of the test was 13.9%. The percentages of corrected mortality of the honeybee pupae, exposed to the test item, A-200SL-OR3-C at the doses of 1.1, 3.3, 10.0, 30.0 and 90.0 µg test item/larva at D15 were: 25.8, 45.2, 80.7, 90.3 and 96.8%, respectively. The percentage of pupal mortality, corrected using Abbott's formula on D15 in the reference item group was 100.0%.
The emergence of adults (emergence rate) at the end of the test (on D22) in the control group was 86.1%. In the groups treated with the test item at the doses of 1.1, 3.3, 10.0, 30.0 and 90.0 µg/larva the adult emergence rates were: 55.6, 44.4, 13.9, 8.3 and 0.0%, respectively.
The median effect doses/concentrations for A-200SL-OR3-C at the end of the assessment (D22) EDx / ECx are equal to:
– ED_{10} value was not determined,
– ED_{20} value is 0.6 µg test item/larva (95% confidence limits: 0.2 – 1.1), corresponding to EC_{20} 4.0 mg/kg (95% confidence limits: 1.5 – 7.1),
– ED_{50} value is 2.5 µg test item/larva (95% confidence limits: 1.5 – 3.7), corresponding to EC_{50} 16.4 mg/kg (95% confidence limits: 9.7 – 24.1).
The NOED value is lower than 1.1 µg test item/larva, corresponding to NOEC 7.1 mg/kg.

Dose [µg test item/larva]	Concen-tration [mg test item/kg food]	Number of tested larvae [no.]	Total mortality (larval and pupal) on day 22 (D22)				
			Number [no.]	[%]	Corr[a] [%]	Number of emerged adults [No.]	Emergence rate [%]
Test item: A-200SL-OR3-C							
0.0 (Control)		36	5	13.9	–	31	86.1
1.1+	7.1	36	16	44.4	35.5	20	55.6
3.3+	21.4	36	20	55.6	48.4	16	44.4
10.0+	64.9	36	31	86.1	83.9	5	13.9
30.0+	194.8	36	33	91.7	90.3	3	8.3
90.0+	584.4	36	36	100.0	100.0	0	0.0
ED_{50} [µg test item/larva]			2.5 *(1.5 – 3.7)**				
EC_{50} [mg/kg]			16.4 *(9.7 – 24.1)**				
NOED [µg test item/larva]			< 1.1				
NOEC [mg/kg]			< 7.1				
Reference item: Technical dimethoate mortality on day 8 (D8)							
7.39	0.053	36	34	94.4	94.3	not determined	

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

A 2.3.2 Effect on arthropods other than bees (KCP 10.3.2)

A 2.3.2.1 Study 1

Comments of zRMS:	The study follows the guideline specified by Mead Briggs *et al.* and according to the principles of GLP. The study is considered to be valid and suitable for the risk assessment.

Reference:	KCP 10.3.2
Report	An extended laboratory test for evaluating the effects of A-200SL-OR3-C on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani - Perez), Paweł Parma, 2019, B/09/19
Guideline(s):	Yes (ESCORT 1, ESCORT 2 guidance documents, Mead-Briggs M.A. et al. 2000; Mead-Briggs M.A. et al., 2010)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Material and Methods

Test item:	name: A-200SL-OR3-C; active ingredients content: acetamiprid: 201.7 g/L, batch number: 3/18; manufacturing date: 29 November 2018; expiry date: 29 November 2020
Biological test system:	The parasitic wasp *Aphidius rhopalosiphi* De Stephani-Perez (Hymenoptera: Braconidae), Aphiidinae
Test conditions:	– temperature: 18 – 21°C – relative air humidity: 61 – 71% – photoperiod: 16 hours light: 8 hours dark – light intensity: mortality assessment and oviposition: 1857 lx fecundity assessment: 6783 lx
Test units:	A test unit consisted of a transparent PMMA cylinder (isolator) with a diameter of 11 cm and a height of 20 cm, put on a plastic pot with a diameter of 12 cm. To assess mortality, the pots contained 7-day-old barley seedlings (8 seedlings per pot). To assess fecundity, the pots contained approximately 20 seedlings of 7-day-old barley infested with the bird cherry-oat aphid, Rhopalosiphum padi (> 100 aphids per pot). To provide good ventilation, the apex of each cylinder and two longitudinal openings on its two sides are covered with fine metal netting. There is a hole in the cylinder to introduce the wasps to the test units. This port is filled with a cotton wool

bung soaked with a 10% solution of fructose in water (w/v).

The aim of the study was to determine the effect of A-200SL-OR3-C on mortality and fecundity of the parasitic wasp, *Aphidius rhopalosiphi*. The endpoints of this test were mortality of the wasps after 48 hours of exposure and fecundity reduction (Pr) 12 days after the oviposition phase.

The effects of A-200SL-OR3-C on mortality and fecundity of *Aphidius rhopalosiphi* in the extended laboratory test are summarized below.

Study group	Parameter (endpoint)					
	Mortality		Fecundity			
Test item [mL/ha]	Total [%]	LR_{50} [mL/ha]	Test item [mL/ha]	Mean no. of mummies/ female	Fecundity reduction Pr [%]	ER_{50} [mL/ha]
Control (0.0)	0.0	–	Control (0.0)	8.1	–	–
7.5	3.3	36.2 (29.2 - 47.7)*	7.5	7.3	9.1	n.d.
15.0	10.0		15.0	6.8	15.7	
30.0+	43.3		30.0	7.6	5.8	
60.0+	73.3		–			
$NOER_{mortality}$		15.0	$NOER_{fecundity}$			≥ 30.0
Reference item	5.0 mL/ha	2.0 g a.i./ha	80.0 [%]			

+: statistically significant differences
*: 95% confidence limits
n.d.: not determined due to mathematical reasons, the ER_{50} value may be higher than 30.0 mL/ha of the A-200SL-OR3-C

Results

In the definitive test, mortality of the control group after 48 hours of the exposure was 0.0%. After 48 hours of the exposure to A-200SL-OR3-C at the rates of 7.5, 15.0, 30.0 and 60.0 mL/ha, the percentages of mortality of *A. rhopalosiphi*, were 3.3, 10.0, 43.3 and 73.3% respectively. At the significance level of 0.05, there were no statistically significant differences in mortality between the group treated with the test item at the rates of 7.5 and 15.0 mL/ha and the control group. On the basis of the obtained mortality results, the LR50 value is equal to 36.2 mL/ha (7.30 g a.i./ha) and $NOER_{mortality}$ value is equal to 15.0 mL/ha (3.03 g a.i./ha). Mortality of the wasps exposed to Bi 58 Top 400 EC at the rate of 5.0 mL/ha was 80.0% after 48 hours. Therefore, the validity criterion was met.

The fecundity assessment showed that the mean number of mummies per female in the control group was 8.1. As for the wasps treated with A-200SL-OR3-C at the rates of 7.5, 15.0 and 30.0 mL/ha, the numbers of mummies/female were 7.3, 6.8 and 7.6, respectively. Fecundity reduction (Pr) in the group treated with A-200SL-OR3-C at the rates of 7.5, 15.0 and 30.0 mL/ha were 9.1, 15.7 and 5.8% respectively.
On the basis of the obtained fecundity results, the ER50 value could not be determined and $NOER_{fecundity}$ value is higher than or equal to 30.0 mL/ha (6.05 g a.i./ha).

The following validity criteria were met during the study:
– after 48 hours mortality of the control group was 0.0% (criterion: a maximum of 10.0%),
– after 48 hours mortality of the group treated with the reference item at the rate of 5.0 mL/ha was 80.0% (criterion: a minimum of 50%),
– all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity),
– the mean number of mummies per female in the control group was 8.1 (criterion: a minimum of 5.0 mummies/female),
– all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring).

Conclusions

On the basis of the obtained results it can be concluded that A-200SL-OR3-C at the rates of 7.5 and 15.0 mL/ha has no adverse effect on mortality. However, the test item at the rates 30.0 and 60.0 mL/ha has adverse effect on mortality. In the fecundity test the test item in all tested rates has no adverse effect on fecundity of the wasps.

A 2.3.2.2 Study 2

Comments of zRMS:	The study follows the guideline specified by Blümel *et al.* (2000) with modifications to create extended laboratory conditions and according to the principles of GLP. The study is considered to be valid and suitable for the risk assessment.

Reference:	KCP 10.3.2
Report	An extended laboratory test for evaluating the effects of A-200SL-OR3-C on the predatory mite, *Typhlodromus pyri* (Sch.), Monika Stalmach, 2019, B/10/19
Guideline(s):	Yes (according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Blümel S. et al., 2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Material and Methods

Test item:	name: A-200SL-OR3-C; active ingredients content: acetamiprid: 201.7 g/L, batch number: 3/18; manufacturing date: 29 November 2018; expiry date: 29 November 2020
Biological test system:	the predatory mite, *Typhlodromus pyri* (Sch.) (Acari: *Phytoseiidae*) – age: 24-hour-old protonymphs – source: a laboratory culture cultivated at the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented by Bias Labs (London, UK), rearing: the mites are reared on the bean, Phaseolus vulgaris L. (*Fabaceae*) infested with the two-spotted spider mite, *Tetranychus urticae*
Test conditions:	– temperature: 24 – 26°C – relative air humidity: 64 – 85% – photoperiod: 16 hours light: 8 hours dark
Test units:	Each test set consisted of a glass tray filled with water and a glass bench containing 5 test units. Leaf discs (ϕ 45 mm) were

floating on the water surface in glass Petri dishes ('island dishes', ϕ 54 mm) with central holes at the bottom (ϕ 6 mm). Water in the test units prevented the mites from escaping.

The aim of the laboratory test was to evaluate the effects of the test item, A-200SL-OR3-C on mortality and reproduction of the predatory mite, *Typhlodromus pyri* (Sch.). The endpoints of this test were mortality of the mites after 7 days of the treatment and the reproduction reduction (Pr) after 14 days of the treatment.

Results

In the definitive test, mortality of the control group after 7 days of exposure was 0.0%. After 7 days of exposure to A-200SL-OR3-C at rates of 0.008, 0.02, 0.06 and 0.17 L/ha the mortality percentages of *T. pyri* were 31.7, 35.0, 71.7 and 86.7%, respectively. On the basis of the obtained results the endpoint regarding LR50 is 0.025 L/ha (5.04 g a.i./ha). The $NOER_{mortality}$ (No Observed Effect Rate) is lower than 0.008 L/ha (1.56 g a.i./ha).
After 7 days of exposure to Bi 58 Top 400 EC at the rate of 9.0 mL/ha (3.6 g a.i./ha), mortality of the mites was 98.3%. Therefore, the validity criterion specified in the Method description was met. The results obtained in the reference item group showed that the test organisms were sensitive to dimethoate.
The mean reproduction rate (Rr) in the control group was 5.7 eggs/female. The mean Rr after 14 days of exposure to A-200SL-OR3-C at rates 0.008 and 0.02 L/ha were 3.8 and 4.4 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by the test item at the rates of 0.008 and 0.02 L/ha were 32.9 and 21.9%, respectively.
On the basis of the obtained results the endpoint regarding ER50 could not be determined and it could be assumed that is higher than 0.02 L/ha (4.37 g a.i./ha). The $NOER_{reproduction}$ is higher than or equal to 0.02 L/ha (4.37 g a.i./ha).

The effects of A-200SL-OR3-C on mortality and reproduction of *Typhlodromus pyri* in the definitive test are summarized below.

Study group [application rate]	Parameter (endpoint)					
	Mortality		Reproduction			
Test item [L/ha]	Total [%]	LR_{50} [L/ha]		Mean number of eggs/ female (Rr) [no.]	Repro-duction reduction Pr [%]	ER_{50} [L/ha]
Control	0.0	0.025 (0.018 – 0.034)**	Control	5.7	–	> 0.02
0.008+	31.7		0.008	3.8	32.9	
0.02+	35.0		0.02	4.4	21.9	
0.06+	71.7					
0.17+	86.7					
$NOER_{mortality}$ < 0.008 [L/ha]			$NOER_{reproduction}$ ≥ 0.02 [L/ha]			
Reference item: Bi 58 Top 400 EC						
Reference item [mL/ha]			9.0			
Active ingredient dimethoate [g/ha]			3.6			
Mortality						
Total [%]			98.3			

+: Statistically significant differences

**: LR_{50} with 95% confidence limit

Conclusions

Based on the results it can be stated that A-200SL-OR3-C at the rates of 0.008, 0.02, 0.06 and 0.17 L/ha had an adverse effect on mortality of the mites. No adverse effect on the mites' reproduction was observed for the groups treated with A-200SL-OR3-C at rates 0.008 and 0.02 L/ha.

A 2.3.2.3 Study 3

Comments of zRMS:	The study follows the guideline specified by Vogt *et al.* and according to the principles of GLP. The study is considered to be valid and suitable for the risk assessment.

Reference: KCP 10.3.2

Report: An extended laboratory test for evaluating the effects of A-200SL-OR3-C on the green lacewings, *Chrysoperla carnea* (Steph.), Monika Stalmach, 2019, RS/11/19

Guideline(s): Yes (according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Vogt H. et al., 2000)

Deviations: No

GLP: Yes

Acceptability: Yes

Material and Methods

Test item:	name: A-200SL-OR3-C; active ingredients content: acetamiprid: 201.7 g/L, batch number: 3/18; manufacturing date: 29.11.2018; expiry date: 11.2020
Biological test system:	the green lacewing, *Chrysoperla carnea* (Steph.), Neuroptera: *Chrysopidae* – age: first instars' larvae (2 – 3 days old) – source: a laboratory culture cultivated at the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented by commercial breeder
Test conditions:	– temperature: 24 – 26°C – relative air humidity: 60.1 – 85.6% – photoperiod: 16 hours light: 8 hours dark
Test units:	Test units for the mortality assessment (exposure unit) consisted of a plastic Petri dishes (diameter: 5 cm) in which there was an leaf disc surrounded by a transparent PMMA cylinder (int. diameter: 4 cm, ext. diameter: 5 cm, height: 5 cm). After spraying a cylinders were placed on each Petri dish. The inner surface of the cylinders was covered with talcum to prevent larvae from climbing up and escaping. Next, one larvae and food, i.e. eggs of the mill moth Ephestia kuehniella were transferred to each treated plate using a fine brush. During the test, food was provided three times a week. The cylinders were covered with cotton gauze for protection and to ensure ventilation.

The aim of the study was to determine the impact of A-200SL-OR3-C on mortality and reproductive capacity of the green lacewing, *Chrysoperla carnea* (Steph.). In a definitive test, four test item application rate of 0.03, 0.08, 0.2 and 0.51 L/ha were used.

The following validity criteria were met during the study:

- pre-imaginal mortality of the control group was 10.0% (criterion: a maximum of 20.0%),
- mean corrected mortality of the reference item group was 92.6% (criterion: a minimum of 50%),
- the mean number of eggs per female per day in the control group (fecundity) was 24.3 (criterion: ≥ 15),
- the mean hatching rate in the control group (fertility) was 95.7 (criterion: ≥ 70%).

The effects of the test item, A-200SL-OR3-C on mortality and reproductive capacity the green lacewings, *Chrysoperla carnea* (Steph.) in the laboratory test are summarized below.

Study group [application rate]	**Parameter (endpoints)**				
	Mortality			**Reproduction**	
Test item [L/ha]	**[%]**	**[%]***	**LR_{50}**	**Mean number of eggs/female/ day [no.]**	**Mean hatching rate [%]**
Control (0.0)	10.0	–	0.08 L/ha (*0.06 – 0.11*)**	24.3	95.7
0.03	20.0	11.1		20.0	88.6
0.08+	56.7	51.9			
0.20+	83.3	81.5			
0.51+	100.0	100.0			
$NOER_{mortality}$	0.03 L/ha				
Bi 58 Top 400 EC					
Reference item [mL/ha]	38.0				
38.0	93.3	92.6	–		

*: the control response of 10.0% was compensated using Abbott's equation [1]
**: LR_{50} with 95% confidence limits
+: Statistically significant differences

Conclusions:

The validity criterion concerning mortality was met, because mortality of the green lacewings, *Chrysoperla carnea* (Steph.) in the control group was 10.0% (≤ 20.0%). The corrected mortality of the green lacewings exposed to the test item at the rates of 0.03, 0.08, 0.20 and 0.51 L of A-200SL-OR3-C/ha after Abbott's correction, were 11.1, 51.9, 81.5 and 100.0%, respectively.
There were statistically significant differences in mortality of the green lacewings in the groups treated with the test item at the rates 0.08, 0.2 and 0.51 L/ha in comparison to the control group.
With respect to the test results, it can be concluded that A-200SL-OR3-C caused an adverse effects on mortality of Ch. carnea (Steph.) at the rates 0.08, 0.2 and 0.51 L/ha of A-200SL-OR3-C.
The LR_{50} value (the application rate at which 50% mortality of the biological test system is observed) is equal to 0.08 L/ha (16.5g a.i./ha). The $NOER_{mortality}$ value is equal to 0.03 L/ha (6.6 g a.i./ha).
The corrected percentage of mortality of *Ch. carnea* (Steph.) exposed to Bi 58 Top 400 EC at rate of 38.0 mL/ha, after Abbott's correction, was 92.6%. The results obtained in the reference item group indicated that the biological test system was sensitive to dimethoate.
The mean number of fertile eggs/female/day in the control group was equal to 24.3 (criterion: ≥ 15.0). The mean numbers of fertile eggs/female/day in the groups treated with A-200SL-OR3-C at the rate of 0.03 L/ha was equal to 20.0, respectively. The mean hatching rate in the control group was 95.7% (criterion: ≥ 70%). The mean hatching rates in the group treated with the test item at rate of 0.03 L/ha was equal to 88.6%, respectively.
Based on the results, it can be presumed that A-200SL-OR3-C at the rate 0.03 L/ha had no effect on the reproductive performance of the lacewings.

A 2.3.2.4 Study 4

Comments of zRMS:	The study follows the guideline specified by Schmuck *et al.* and according to the principles of GLP. The study is considered to be valid and suitable for the risk assessment.

Reference:	KCP 10.3.2
Report	An extended laboratory test for evaluating the effects of A-200SL-OR3-C on the ladybird beetle, *Coccinella septempunctata* L., Monika Stalmach, 2019, RS/12/19
Guideline(s):	Yes (according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Schmuck et al., 2000))
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Material and Methods

Test item:	name: A-200SL-OR3-C; active ingredients content: acetamiprid: 201.7 g/L, batch number: 3/18; manufacturing date: 29.11.2018; expiry date: 11.2020
Biological test system:	the ladybird beetle, *C. septempunctata* L. (Arthropoda: *Coccinellidae*) – age: 3-day-old larvae – source: a laboratory culture cultivated at the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented by commercial breeder
Test conditions:	– temperature: 22.5 – 27.0°C, – relative air humidity: 58.0 – 88.9%, – photoperiod: 16 hours light: 8 hours dark
Test units:	Test units (exposure units) consisted of a plastic Petri dish in which there was an leaf disc surrounded by a transparent PMMA cylinder (ext. diameter: 5 cm; height: 4 cm). The inner walls of the cylinders were coated with talcum in order to prevent both ladybird larvae and aphids (ladybirds' food) from climbing up the walls. To assess reproductive performance of the ladybird beetles, glass terrariums (dimensions: 20 x 20 x 30 cm) were used as reproduction units.

Test units (exposure units) consisted of a plastic Petri dish in which there was an leaf disc surrounded by a transparent PMMA cylinder (ext. diameter: 5 cm; height: 4 cm). The inner walls of the cylinders were coated with talcum in order to prevent both ladybird larvae and aphids (ladybirds' food) from climbing up the walls. To assess reproductive performance of the ladybird beetles, glass terrariums (dimensions: 20 x 20 x 30 cm) were used as reproduction units.

The following validity criteria were met during the study:
– pre-imaginal mortality of the control group was 7.5% (criterion: a maximum of 30.0%),
– mean corrected mortality of the reference item group was 94.6% (criterion: a minimum of 40%),
– fertility (the mean number of fertile eggs/female/day) in the control group was 4.9 (criterion: ≥ 2 fertile eggs/female).

The effects of the test item, A-200SL-OR3-C on mortality and reproductive capacity of the ladybird beetle, *Coccinella septempunctata* L. in the laboratory test are summarized below:

Study group [application rate]	Parameters (endpoints)				
	Mortality		Reproduction		
Test item [L/ha]	[%]	LR_{50} [L/ha]	Mean no. of eggs/female/day	Mean no. of fertile eggs/female/day	Reproduction reduction Pr [%]
Control (0.0)	0.0[a]	0.032 (0.024 – 0.039)[c]	7.7	4.9	–
0.03[+]	45.9[a]		15.0	10.6	-116.3[d]
0.08[+]	91.9[a]				
0.20[+]	100.0[a]				
0.51[+]	100.0[a]				
$NOER_{mortality}$	< 0.03 [L/ha]				
Bi 58 Top 400 EC					
Reference item [mL/ha]	94.6[b]	–			
8.0					

[a]: control group mortality 7.5% was compensate using the Abbott's equation [1]
[b]: Mortality of the reference item was corrected according to Schneider-Orelli's formula [9] due to the loss of two individuals during the course of the study
[c]: LR_{50} with 95% confidence limits
[d]: The negative value means that in the tested rate there was higher mean number of fertile eggs per viable female per day than in the control group
[+]: statistical significant differences

Conclusions

The validity criterion concerning mortality was met, because mortality of the ladybird beetle, *Coccinella septempunctata* L. in the control group was equal to 7.5% (≤ 30.0%). The corrected mortality of the ladybird beetles exposed to the test item at the rates 0.03, 0.08, 0.2 and 0.51 L of A-200SL-OR3-C/ha was 45.9, 91.9, 100.0 and 100.0%, respectively.
With respect to the test results, it can be concluded that A-200SL-OR3-C caused an adverse effects on mortality of *C. septempunctata* L. at the all rates used in the study.
Based on the obtained mortality results, the LR_{50} value (the application rate at which 50% mortality of the test system is observed) is equal to 0.032 L of A-200SL-OR3-C/ha (6.45 g a.i./ha). The $NOER_{mortality}$ is lower than 0.03 L of A-200SL-OR3-C/ha (6.6 g a.i./ha).
The corrected mortality of the ladybird beetles exposed to the reference item at the rate of 8.0 mL of Bi 58 Top 400 EC/ha was equal to 94.6%. Therefore, the validity criterion was met. The results showed that the insects were sensitive to dimethoate.
The mean number of fertile eggs/female/day in the control group was 4.9 (criterion: ≥ 2

eggs/female/day).. The mean numbers of fertile eggs/female/day in the group treated with the of A-200SL-OR3-C at the rate of 0.03 L/ha was equal to 10.6 and it refers to (-116.3%) reproduction reduction. The negative value means that in the tested rate there was higher mean number of fertile eggs per viable female per day than in the control group. It can be concluded that A-200SL-OR3-C at the rate of 0.03 L/ha had no adverse effect on the reproduction capacity of the ladybird beetle

A 2.3.2.5 Study 5

Comments of zRMS:	The study follows the guideline specified by Mead Briggs *et al.* and according to the principles of GLP. The study is considered to be valid and suitable for the risk assessment.

Reference:	KCP 10.3.2
Report	A-200SL-OR3-C – Aged-residue extended laboratory tests to determine effects on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera, Braconidae), James Stevens, 2019, CIE-19-11
Guideline(s):	Mead- Briggs et al. (2000). A laboratory test for evaluating the effects of plant protection products on the parasitic wasp, *Aphidius rhopalosiphi*
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Material and Methods

Test item:	name: A-200SL-OR3-C; active ingredients content (analysed): acetamiprid: 204.4 g/L, batch number: 2/19; manufacturing date: 03.2019; expiry date: 03.2021
Biological test system:	The test insects (*Aphidius rhopalosiphi*) were obtained from an in-house culture, originally established using wasps from a commercial supplier (Katz Biotech AG, Baruth, Germany)
Test conditions:	– temperature: 20.2 – 21.0°C (77 DAT), 20.2 – 20.9°C (91 DAT), – relative air humidity: 67.0 – 78.0%, – photoperiod: 16 hours
Test units:	The arenas comprised circular frames made from clear acrylic tubing (these were of approx. 5.1 cm internal diameter and 15 mm deep) and held in place with 3 elastic bands. Holes (four in number and ca. 8 mm in diameter) had been drilled through the side wall of the frame to provide ventilation and 3 of these were covered with nylon netting (0.5 mm x 0.5 mm mesh). The fourth hole was left uncovered as an access hole for the introduction of the parasitoids and was then sealed with a cotton wool bung. The treated leaves were laid, with their upper (treated) surface exposed, on glass plates (7.5 cm x 7.5 cm), ensuring that the glass surface inside the test arenas was fully covered with the leaves.

The test item in this study was A-200SL-OR3-C, a soluble concentrate formulation containing acetamiprid (nominally 200 g/L). The aim was to evaluate the effects of both freshly-dried and field-aged residues of this test item in a series of bioassays with the parasitic wasp *Aphidius rhopalosiphi*, carried out under extended laboratory test conditions. Extended laboratory bioassays were carried out using leaves collected from the treated plants immediately after residues had dried (approximately 1 h after treatment), hereafter referred to as 0 days after treatment (DAT), and then at 14, 28, 49, 77 and 91 DAT.

The results of assessments of mortality and reproduction are summarised below. No unacceptable effects were seen for the test-item treatment in bioassays at 77 and 91 DAT.
The percentage mortality of wasps (n = 40 per treatment) at 48 h in bioassays commencing 0, 14, 28, 49, 77 and 91 DAT.

Bioassay initiated	Treatment	Test item rate (L product/ha)	% mortality [a)] (48 h)	Corrected % mortality [b)] (48 h)
0 DAT	Control	-	2.5	-
	A-200SL-OR3-C	0.51	100 *	100
	Toxic reference	-	100 *	100
14 DAT	Control	-	0.0	-
	A-200SL-OR3-C	0.51	100 *	100
28 DAT	Control	-	2.5	-
	A-200SL-OR3-C	0.51	97.5 *	97.4
49 DAT	Control	-	2.5	-
	A-200SL-OR3-C	0.51	97.5 *	97.4
77 DAT	Control	-	2.5	-
	A-200SL-OR3-C	0.51	22.5 *	20.5
91 DAT	Control	-	5.0	-
	A-200SL-OR3-C	0.51	17.5	13.2

a) For each bioassay, the results were compared to the respective control; an asterisk (*) indicates where there were significant differences (Fisher's Exact Binomial Test, one-sided, > control, $\alpha = 0.05$).

b) Derived using Abbott's formula. A positive value indicates an increase in mortality, relative to the control.

T

he mean number of mummies obtained per surviving female (n) wasp following a 24 h oviposition period in bioassays commencing at 77 and 91 DAT.

Bioassay initiated	Treatment	Test-item rate (L/ha)	Number ♀ wasps evaluated	Mean number mummies per surviving female [a]	Standard deviation	Effect on reproduction [b] [%]
77 DAT	Control	-	15	52.7	12.2	-
	A-200SL-OR3-C	0.51	14	53.1	10.8	-0.6
91 DAT	Control	-	13	36.9	9.8	-
	A-200SL-OR3-C	0.51	14	36.1	11.0	2.3

a) For each bioassay, results for the test-item treatment were compared to the respective control by two-sample t-test (one-sided, < control, $\alpha = 0.05$). Values did not differ significantly from the control.

b) Percentage change in reproduction, relative to the respective control. A positive value indicates a decrease in reproduction, a negative value an increase.

Since the A-200SL-OR3-C treatment had resulted in < 50% reduction in both wasp survival and reproduction, relative to the control, in two consecutive bioassays, the testing programme was ended.

Validity criteria:
a) mortality in the control treatment should not exceed 13% (i.e. 5 wasps from 40) at 48 h.
b) mortality in the toxic reference treatment should be > 50% at 48 h.
c) for the reproduction assessments, the mean number of mummies in the control treatment should be > 5.0 per female and there should not be more than two zero values in the control treatment.

All of these validity criteria were met.

Conclusions
The effects of freshly-dried and field-aged foliar residues of A-200SL-OR3-C on the parasitic wasp, *Aphidius rhopalosiphi* were evaluated under extended laboratory test conditions. When applied to dwarf French bean plants at a rate equivalent to 0.51 L product/ha, both 77-day and 91-day field-aged residues resulted in no unacceptable effects on either the survival or the subsequent reproductive capacity of the wasps, (i.e. < 50% corrected mortality and < 50% reduction in reproduction, relative to the control).

A 2.3.2.6 Study 6

Comments of zRMS:	The study follows the guideline specified by Blümel *et al.* and according to the principles of GLP. The study is considered to be valid and suitable for the risk assessment.

Reference: KCP 10.3.2

Report: A-200SL-OR3-C – Aged-residue extended laboratory tests to determine effects on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae), Lisa Fallowfield, 2019, CIE-19-10

Guideline(s):	Blümel et al. (2000). Laboratory residual contact test with the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) for regulatory testing of plant protection products.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Material and Methods

Test item:	name: A-200SL-OR3-C; active ingredients content (analysed): acetamiprid: 204.4 g/L, batch number: 2/19; manufacturing date: 03.2019; expiry date: 03.2021
Biological test system:	The predatory mite, *Typhlodromus pyri*, was obtained from a culture maintained at the Test Facility, based upon a strain of mites originally obtained in April 1995 from a commercial supplier (P.K. Nützlingszuchten, Welzheim, Germany). The culture had been supplemented with further mites from the same source in 1996 and 1997.
Test conditions:	– temperature: 23-27ºC – relative air humidity: 60-90% – photoperiod: 16 hours
Test units:	The mites were reared on arenas to a design described by Overmeer et al. (1982). These consisted of a rectangular tile (10 cm x 20 cm in area and 1.5 mm thick) made from black PVC, with a layer of clear PVC film stretched over it. The mites were placed on a tile, which was rested on the upturned modified lid of a Perspex box, the base of which was filled with purified water. A strip of chromatography paper (10 cm x 30 cm), with two square 'windows' (7 cm x 7 cm) cut in it was laid over the tile. The ends of the paper were submerged in the water so that it became saturated by wicking action.

The test item in this study was A-200SL-OR3-C, a soluble concentrate formulation containing acetamiprid (nominally 200 g/L). The aim of this study was to determine the effects of both freshly-dried and field-aged residues of A-200SL-OR3-C on the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae), under extended laboratory test conditions. Extended laboratory bioassays were carried out using leaves collected from the treated plants immediately after residues had dried (approximately 1 h after treatment), hereafter referred to as 0 days after treatment (DAT), and then at 14 and 28 DAT.

Summary of mite mortality observed in the bioassays initiated 0, 14 and 28 days after treatment (DAT):

Bioassay initiated	Treatment	Test item rate (L/ha)	Mean % mortality at 7 days [a]	Corrected % mortality at 7 days [b]	Mean number eggs/female (7-14 days) [c]	Change in reproduction [%] [d]
0 DAT	Control	-	10	-	~	-
	A-200SL-OR3-C	0.51	78 *	75.6	~	~
	Toxic reference	-	100 *	100	~	~
14 DAT	Control	-	15	-	9.3	-
	A-200SL-OR3-C	0.51	18	3.5	10.3	-10.7
28 DAT	Control	-	12	-	9.3	-
	A-200SL-OR3-C	0.51	13	1.1	7.6	17.6

a) For each bioassay, treatment mortalities were compared to the control using Chi^2 2x2 table test ($\alpha = 0.05$, one-sided, > control), a statistically significant effect is denoted by an asterisk (*).

b) Mortality corrected for respective control treatment deaths using Abbott's formula. A positive value indicates an increase.

c) For each bioassay, treatments were compared to the control by Student t-test for homogenous variances ($\alpha = 0.05$, one-sided, < control), there were no statistically significant differences.

d) Percentage change in numbers of eggs per female, relative to the respective control. A positive value indicates a decrease and a negative value indicates an increase, in egg production.

~ indicates no assessments were made for this treatment.

A summary of the reproduction of mites in bioassays initiated 14 and 28 days after treatment (DAT):

Bioassay initiated	Treatment	Test item rate (L/ha)	Mean number of eggs per female [a] (7-14 DAI)	% change in reproduction, relative to the control [b]
14 DAT	Control	-	9.3	-
	A-200SL-OR3-C	0.51	10.3	-10.7
28 DAT	Control	-	9.3	-
	A-200SL-OR3-C	0.51	7.6	17.6

a) For each bioassay, treatments were compared to the control by Student t-test for homogenous variances ($\alpha = 0.05$, one-sided, < control), there were no statistically significant differences.

b) A positive value indicates a decrease and a negative value indicates an increase, in egg production.

Validity criteria:

a) mortality in the control treatment over the initial 7 days of a bioassay should not exceed 20%.
b) mortality in the toxic reference treatment should be 50-100%.
c) the mean cumulative number of eggs produced between 7 and 14 days should be equal to or exceed 4.0 per female in the control treatment.

All of these criteria, where relevant, were met in the 0, 14 and 28 DAT bioassays.

Conclusions

The effects of freshly-dried and field-aged foliar residues of A-200SL-OR3-C on the predatory mite

Typhlodromus pyri were evaluated under extended laboratory test conditions. When applied to dwarf French bean plants at a rate equivalent to 0.51 L product/ha (nominally 102 g a.s./ha), both 14-day-old and 28-day field-aged residues resulted in no unacceptable effects on either the survival or the subsequent reproductive capacity of the mites, (i.e. < 50% corrected mortality and < 50% reduction in reproduction, relative to the control).

A 2.3.2.7 Study 7

Comments of zRMS:	The study follows the guideline specified by Vogt *et al.* and according to the principles of GLP. The study is considered to be valid and suitable for the risk assessment.

Reference:	KCP 10.3.2
Report	A-200SL-OR3-C – A series of aged-residue extended laboratory tests to determine effects on the green lacewing, *Chrysoperla carnea* (Neuroptera, Chrysopidae), Russell Vaughan, 2019, CIE-19-13
Guideline(s):	Vogt et al. (2000). Laboratory method to test effects of plant protection products on larvae of *Chrysoperla carnea* (Neuroptera: Chrysopidae)..
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Material and Methods

Test item:	name: A-200SL-OR3-C; active ingredients content (analysed): acetamiprid: 204.4 g/L, batch number: 2/19; manufacturing date: 03.2019; expiry date: 03.2021
Biological test system:	Eggs of the green lacewing, *Chrysoperla carnea* Steph. (Neuroptera, Chrysopidae), were obtained from a commercial supplier (BIAS Labs Ltd., Fife, UK) or from a culture maintained at the Test Facility (originally sourced from BIAS Labs Ltd., Fife, UK). For each bioassay, a cohort of eggs laid over a 24-h period was used.
Test conditions:	– temperature: 24.4-25.7ºC – relative air humidity: 60-73% – photoperiod: 16 hours
Test units:	Larvae were exposed to dry residues on excised French bean leaves, which were used to line the floor of simple test arenas (Each comprised a square glass plate (7.5 cm x 7.5 cm), a Perspex® supporting plate of similar size, with a 5-cm-diameter hole cut through it, and an acrylic cylinder of 5 cm diameter. The treated leaf was laid on the glass plate with its adaxial (upper) treated surface exposed facing upwards and the Perspex sheet was placed on top. This was held firmly in place using elastic bands. The petiole of the leaf was wrapped in wet cotton wool and draped into a water trough.

The test item in this study was A-200SL-OR3-C, a soluble concentrate formulation containing acetamiprid (nominally 200 g/L). The aim of this study was to evaluate the effects of both freshly-

dried and field-aged foliar residues of the test item on the green lacewing, *Chrysoperla carnea* Steph. (Neuroptera: Chrysopidae), under extended laboratory test conditions.

The results of the mortality assessments are summarised below.

Bioassay started [a]	Treatment	Test-item rate [b] (L/ha)	% pre-imaginal mortality [c]	Corrected % pre-imaginal mortality [d]
0 DAT	Control	-	10.0	-
	A-200SL-OR3-C	0.51	87.5 *	86.1
	Toxic reference	-	85.0 *	83.3
14 DAT	Control	-	0.0	-
	A-200SL-OR3-C	0.51	55.0 *	55.0
28 DAT	Control	-	10.0	-
	A-200SL-OR3-C	0.51	17.5	8.3
42 DAT	Control	-	5.0	-
	A-200SL-OR3-C	0.51	12.5	7.9

a) Timing of bioassays in terms of days after application of test-item treatment (DAT).
b) Application rate of the test item.
c) For each bioassay, pre-imaginal mortality in the test item treatment and the toxic reference treatment was compared to the control using Fisher's Exact Binomial test (one-sided, > control, $\alpha = 0.05$). An asterisk (*) indicates where differences were significant.
d) Corrected mortalities were calculated using Abbott's formula.

The results of the reproduction assessments are summarised below.

Bioassay started [a]	Treatment	Test-item rate [b] (L/ha)	Mean no. eggs/♀/ day [c]	Mean % egg viability [d]	Mean no. viable eggs/♀/ day
28 DAT	Control	-	22.6	91.3	20.6
	A-200SL-OR3-C	0.51	22.2	85.0	18.9
42 DAT	Control	-	33.3	92.1	30.6
	A-200SL-OR3-C	0.51	45.5	90.5	41.2

a) Timing of bioassays in terms of days after application of test-item treatment (DAT).
b) Application rate of the test item.
c) Based on two 24-h long assessments made for each oviposition box in each treatment.
d) Based on all eggs laid on the fibrous tissue sheet lining the lid of each oviposition box.

In the 28 and 42 DAT bioassays, the mean numbers of eggs produced in all the treatments evaluated was ≥ 15 eggs/female/day and the mean egg viability was ≥ 70%. These two thresholds are currently viewed as being indicative of no harmful treatment effects.

Validity criteria

a) Pre-imaginal mortality in the control treatment should ≤ 20% (i.e. 8 lacewings from 40).
b) Corrected pre-imaginal mortality in the toxic reference treatment should be ≥ 50% (0 DAT bioassay only).
c) For the reproduction assessments, the mean egg production in the control should be ≥ 15 eggs per female per day and mean viability of the eggs should be ≥ 70%.

All of these criteria were met throughout the study, where applicable.

Conclusions

The effects of both fresh and aged foliar residues of A-200SL-OR3-C on the green lacewing, *Chrysoperla carnea*, were evaluated under extended laboratory conditions. When applied at a rate equivalent to 0.51 L product/ha, fresh (0-day-old) and 14-day-old foliar residues of A-200SL-OR3-C had unacceptable effects on the survival of the lacewings. However, both 28-day-old and 42-day-old residues resulted in no unacceptable effects on either the survival or the subsequent reproductive capacity of the lacewings.

A 2.3.2.8 Study 8

Comments of zRMS:	The study follows the guideline specified by Schmuck *et al.* and according to the principles of GLP. The study is considered to be valid and suitable for the risk assessment.

Reference:	KCP 10.3.2
Report	A-200SL-OR3-C – A series of aged-residue extended laboratory test to determine effects on the ladybird beetle, *Coccinella septempunctata* (Coleoptera: Coccinellidae)., Russell Vaughan, 2019, CIE-19-12
Guideline(s):	Schmuck et al. (2000). A Laboratory test system for assessing effects of plant protection products on the plant-dwelling insect *Coccinella septempunctata* L. (Coleoptera: Coccinellidae).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Material and Methods

Test item:	name: A-200SL-OR3-C; active ingredients content (analysed): acetamiprid: 204.4 g/L, batch number: 2/19; manufacturing date: 03.2019; expiry date: 03.2021
Biological test system:	For each bioassay, a cohort of eggs of the ladybird beetle, *C. septempunctata*, were obtained from a commercial source (Katz Biotech AG, Baruth, Germany). Ladybird larvae hatching over a 24 h period were used for each bioassay and were taken when they were 3-4 days old (14 DAT and 56 DAT bioassays) or 4-5 days old (0 DAT and 42 DAT bioassays).
Test conditions:	– temperature: 24.7-25.1ºC – relative air humidity: 60-74% – photoperiod: 16 hours
Test units:	Larvae were exposed to dry residues on excised French bean leaves, which were used to line the floor of simple test arenas. Each comprised a square glass plate (7.5 cm x 7.5 cm), a Perspex® supporting plate of similar size, with a 5-cm-diameter hole cut through it, and an acrylic cylinder of 5 cm

diameter. The treated leaf was laid on the glass plate with its adaxial (upper) treated surface exposed facing upwards and the Perspex sheet was placed on top. This was held firmly in place using elastic bands. The petiole of the leaf was wrapped in wet cotton wool and draped into a water trough. Separate water troughs were used for the different treatments.

The test item in this study was A-200SL-OR3-C, a soluble concentrate formulation containing acetamiprid (nominally 200 g/L). The aim of this study was to evaluate the effects of both freshly-dried and field-aged foliar residues of the test item on the ladybird beetle, *Coccinella septempunctata* L. (Coleoptera: Coccinellidae), under extended laboratory test conditions.

Results

The results of the mortality assessments are summarised below.

Bioassay started [a)]	Treatment	Test-item rate [b)] (L/ha)	% pre-imaginal mortality [c)]	Corrected % pre-imaginal mortality [d)]
0 DAT	Control	-	7.5	-
	A-200SL-OR3-C	0.51	92.5 *	91.9
	Toxic reference	-	100 *	100
14 DAT	Control	-	7.5	-
	A-200SL-OR3-C	0.51	95.0 *	94.6
42 DAT	Control	-	25.0	-
	A-200SL-OR3-C	0.51	52.5 *	36.7
56 DAT	Control	-	15.0	-
	A-200SL-OR3-C	0.51	17.5	2.9

a) Timing of bioassays in terms of days after application of test-item treatment (DAT).

b) Application rate of the test item.

c) For each bioassay, pre-imaginal mortality in the test item treatment and the toxic reference treatment was compared to the control using Fisher's Exact Binomial test (one-sided, > control, $\alpha = 0.05$). An asterisk (*) indicates where differences were significant.

d) Corrected mortalities were calculated using Abbott's formula.

The results of the reproduction assessments are summarised below.

Bioassay started [a)]	Treatment	Test-item rate [b)] (L/ha)	Mean no. eggs/♀/ day	Mean % egg viability	Mean no. viable eggs/♀/ day
42 DAT	Control	-	27.6	67.6	18.7
	A-200SL-OR3-C	0.51	34.4	76.4	26.3
56 DAT	Control	-	18.7	57.3	10.7
	A-200SL-OR3-C	0.51	14.9	73.8	11.0

a) Timing of bioassays in terms of days after application of test-item treatment (DAT).

b) Application rate of the test item.

Validity criteria:

a) Pre-imaginal mortality (this includes dead larvae, pupae and adults dying during emergence from their pupae) in the control treatment should not exceed 30%;
b) The level of mortality in the toxic reference treatment should be ≥ 50%;
c) Mean egg production should be > 2 viable eggs/female/day in the control treatment.

All of these criteria were met throughout the study, where applicable.

Conclusions

The effects of both fresh and aged foliar residues of A-200SL-OR3-C on the ladybird beetle, *Coccinella septempunctata*, were evaluated under extended laboratory conditions. When applied at a rate equivalent to 0.51 L product/ha, fresh (0-day-old) and 14-day-old foliar residues of A-200SL-OR3-C had unacceptable effects on the survival. However, both 42-day-old and 56-day-old residues resulted in no unacceptable effects on either the survival or the subsequent reproductive capacity of the ladybirds.

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

A 2.4.1.1.1 Study 1

Comments of zRMS:	The study was conducted to OECD guideline 222 and according to the principles of GLP. No deviations to the guideline were noted. The study is considered to be reliable and suitable for the risk assessment.
Reference:	KCP 10.4.1
Report	Report A-200SL-OR3-C: Earthworm Reproduction Test (*Eisenia andrei*) according to the OECD Guideline No. 222 (2016) STUDY CODE: G/147/18 Institute of Industrial Organic Chemistry Branch Pszczyna; Wołany M., 2019a
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 222 (2016): "Earthworm Reproduction Test *(Eisenia fetida/Eisenia andrei)"*.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Material and Methods

Test item:	name: A-200SL-OR3-C; active ingredients content (analysed): acetamiprid: 201.7 g/L, batch number: 3/18; manufacturing date: 11.2018; expiry date: 11.2020
Test organism:	The experiment was performed on the adult earthworm, *Eisenia andrei* obtained from a synchronized culture cultivated at the Institute of Industrial Organic Chemistry, Branch

	Pszczyna, Department of Ecotoxicological Studies, Laboratory of Soil Toxicology [SOP/G/34]. The synchronized culture was obtained by placing adult earthworms in a breeding box containing a fresh substrate to allow the production of cocoons. After 4 weeks, the adults were removed from the box. All earthworms hatched from the cocoons were used for the purpose of the experiment when they reached maturity, i.e. when they were about 5 months old.
Artificial soil	Components: - 10% sphagnum peat - 20% kaolin clay - 70% air-dried quartz sand maximum water holding capacity: 53.42% pH: 5.57. soil dry weight content: 88.0%
Test conditions:	– temperature: 18-22ºC - controlled light – dark cycles (16h : 8h)
Tested concentrations:	Nine concentrations of the test item were used in the experiment (0.18, 0.32, 0.56, 1.0, 1.8, 3.3, 5.6, 10.0 and 18.0 mg of the test item/kg of dry weight of the artificial soil). There were four replicates of each test concentration. At the same time, an untreated control group (eight replicates) was introduced to the soil without the test item. The test item in the form of a aqueous solution was mixed with a suitable amounts of the artificial soil.
Study duration:	8 weeks
Observations:	After 4 weeks: pathological changes. mortality After 8 weeks: number of juveniles hatched from the cocoons
Endpoints:	NOEC, LOEC, EC_{10}, EC_{20}, EC_{50}, LC_{50}

The aims of the study were to assess the impact of the test item on reproduction of the earthworm, *Eisenia andrei* and to determine the EC10, EC20, EC50, and NOEC.

Results

On the basis of the results, it was concluded that after 4 weeks, at the control group no mortality of adult earthworms was noticed. At concentrations ranging from 0.18 to 18.0 mg of the test item/kg dry weight of artificial soil, after 4 weeks of exposure to the test item, mortality of the adult earthworms was ranging from 2.5 to 17.5%.

The concentration of the test item causing 50% mortality of the adult earthworms (LC50) was above 18.0 mg of the test item/kg dry weight of artificial soil (3.08 mg of acetamiprid /kg dry weight of artificial soil).

No changes in the appearance (morphology) and behaviour of the adult earthworms were noticed.

After the application of the test item at the concentrations ranging from 0.18 to 18.0 mg of the test item/kg dry weight of artificial soil, the body weight decrease was between 7.7 and 10.9%. As for the control group, the body weight decrease was equal to 8.7%.

After 8 weeks of the experiment, the obtained results led to the following conclusions:
After the application of the test item at the concentrations ranging from 0.18 to 18.0 mg of the test item/kg dry weight of the artificial soil, the mean number of juveniles was between 45.5 – 85.8 per replicate. The mean number of juveniles in the control group was equal to 71.3 per replicate.

After 8 weeks of the experiment, it was concluded that A-200SL-OR3-C had statistically significant impact on reproduction of the earthworms at concentrations between 5.6 and 18.0 mg of the test item/kg dry weight of artificial soil.
The endpoint values showing the impact of the test item on reproduction and survival of adult earthworms are presented in the table given below

Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg of acetamiprid/kg dry weight of artificial soil]
EC_{10}	2.87 (1.04 – 4.51)	0.49 (0.18 – 0.77)
EC_{20}	6.58 (4.05 – 9.14)	1.13 (0.69 – 1.57)
EC_{50}	> 18.00	> 3.08
NOEC (reproduction)	3.30	0.57
LOEC (reproduction)	5.60	0.96
LC_{50}	> 18.0	> 3.08
NOEC (survival)	10.00	1.71
LOEC (survival)	18.00	3.08

Validity criteria:

The results are considered valid because the following criteria were satisfied in the controls:

- each replicate produced 71.3 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment),
- the coefficient of variation of reproduction was 23.3% (criterion: ≤ 30%),
- adult mortality over the initial 4 weeks of the experiment was 0.0% (criterion: ≤ 10%).

Conclusions

In the 56 - day Earthworm reproduction study with Leptosar 200 SL, the lowest endpoint (EC_{10}) of 0.49 mg ai/kg dws was obtained and thus, it is proposed to be used in the risk assessment.

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

Not relevant.

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1 KCP 10.4.2.1 Species level testing

A 2.4.2.1.1 Study 1

Comments of zRMS:	The study was conducted to OECD guideline 232 and according to the principles of GLP. The study is considered to be reliable and suitable for the risk assessment.

Reference:	KCP 10.4.2/01
Report	Report A-200SL-OR3-C: Collembolan *(Folsomia candida)* Reproduction Test according to OECD Guideline No. 232 (2016) STUDY CODE: G/148/18Institute of Industrial Organic Chemistry Branch Pszczyna; Wołany M., 2019b
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 232 (2016): "Collembolan reproduction test in soil" [1] and the Standard Operating Procedure SOP/G/87: "Collembolan *(Folsomia candida)* reproduction test".
Deviations:	Yes. Deviations from the OECD Guideline No. 232 (2016): - culturing of collembolans took place in plastic containers containing an artificial substrate consisting of plaster and charcoal in ratio 9:1 and not 10:1 or 8:1 as is mentioned in OECD Guideline No. 232 (2016) - at the end of the test the soil moisture content was determined by drying small sample of the artificial soil in 105°C instead of weighing the test vessels as it is mentioned in OECD Guideline No. 232 (2016) - physiological or pathological symptoms or distinct changes in behavior were not described The deviations did not affect the study results.
GLP:	Yes
Acceptability:	Yes

Material and Methods

Test item:	name: A-200SL-OR3-C; active ingredients content (analysed): acetamiprid: 201.7 g/L, batch number: 3/18; manufacturing date: 11.2018; expiry date: 11.2020
Test organism:	The collembolan, *Folsomia candida* obtained from a standard laboratory culture at the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna, Laboratory of Soil Toxicology. The collembolans used in the study were 9 – 12 days old
Artificial soil	Components: - 5% sphagnum peat - 20% kaolin clay - 75% air-dried quartz sand

maximum water holding capacity: 31.53%
pH: 5.53.
soil dry weight content: 94.8%

Test conditions: – temperature: 20.0-21.5 °C
- controlled light – dark cycles (16h : 8h)

Tested concentrations: Nine concentrations of the test item were used in the experiment (0.18, 0.32, 0.56, 1.0, 1.8, 3.3, 5.6, 10.0 and 18.0 mg of the test item/kg of dry weight of the artificial soil).

There were four replicates of each test concentration.

At the same time, an untreated control group (eight replicates) was introduced to the soil without the test item.

The test item in the form of a aqueous solution was mixed with a suitable amounts of the artificial soil.

Study duration: 28 days

Observations: After 28 days: mortality, number of juveniles

Endpoints: NOEC, LOEC, EC_{10}, EC_{20}, EC_{50}, LC_{50}

The aims of the study were to assess the impact of the test item on reproduction of the collembolan, *Folsomia candida* and to determine the EC10, EC20, EC50, and NOEC.

Results

Mortality at the concentrations ranging from 0.18 to 18.0 mg/kg dry weight of the artificial soil ranged from 0.0 to 100.0%. As for the control group, it was equal to 12.5%.
The concentration of the test item causing a 50% mortality of adults within the exposure period (LC50) was equal to 2.57 mg/kg dry weight of the artificial soil (equal to 0.44 mg of acetamiprid / kg dry weight of the artificial soil).
The endpoint values showing the impact of the test item on the survival of adult collembolans are presented in the table given below.

Endpoint	Value [mg test item /kg dry weight of the artificial soil]	Value [mg of acetamiprid /kg dry weight of the artificial soil]
LC_{10}	1.20 (0.94 – 1.44)	0.21 (0.16 – 0.25)
LC_{20}	1.56 (1.28 – 1.82)	0.27 (0.22 – 0.31)
LC_{50}	2.57 (2.24 – 2.95)	0.44 (0.38 – 0.51)
NOEC	1.00	0.17

After the exposure of collembolans to the test item at the concentrations ranging from 0.18 to 18.0 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 14.5 – 1129.0 per replicate. As for the control group, the number of juveniles was equal to 1011.6 per replicate.
The endpoint values showing the impact of the test item on reproduction of *Folsomia candida* are presented in the table given below.

Endpoint	Value [mg test item /kg dry weight of the artificial soil]	Value [mg of acetamiprid /kg dry weight of the artificial soil]
EC_{10}	1.10 (0.60 – 1.79)	0.19 (0.10 – 0.31)
EC_{20}	1.55 (0.90 – 2.56)	0.27 (0.15 – 0.44)
EC_{50}	2.97 (1.82 – 5.47)	0.51 (0.31 – 0.94)
NOEC	1.00	0.17

Validity criteria:

The results are considered valid because the following criteria were satisfied in the controls:

- mean adult mortality: 12.5% (criterion: ≤ 20%),
- the mean number of juveniles per vessel at the end of the test: 1011.6 (criterion: ≥ 100 juveniles at the end of the test),
- the coefficient of variation calculated for the number of juveniles: 14.3 (criterion: ≤ 30%).

Conclusions

In the 28 - day collembolan reproduction study with Leptosar 200 SL, the lowest endpoint (NOEC) of 0.17 mg ai/kg dws for both effects – mortality and reproduction was obtained and thus, it is proposed to be used in the risk assessment.

A 2.4.2.1.2 Study 2

Comments of zRMS:	The study was conducted to OECD guideline 226 and according to the principles of GLP. The study is considered to be reliable and suitable for the risk assessment.

Reference:	KCP 10.4.2/02
Report	Report A-200SL-OR3-C: Predatory mite (*Hypoaspis* (*Geolaelaps*) *aculeifer*) reproduction test in soil according to the OECD Guideline No. 226 (2016) STUDY CODE:G/149/18 Institute of Industrial Organic Chemistry Branch Pszczyna; Wołany M., 2019c
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 226 (2016): "Predatory mite *(Hypoaspis (Geolaelaps) aculeifer)* reproduction test in soil"
Deviations:	Yes. Deviations from the OECD Guideline No. 226 (2016): 1. According to the OECD Guideline No. 226 (2016) the water content of the soil substrate should be maintained throughout the test by weighing and if

needed re-watering the vessels periodically. In the study to maintain proper moisture content, a small sample of soil was drying at 105°C and re-weighing at the beginning, after 7 days of the test and at the end of the test.

2. Due to the use of the temperature extraction method, there was no need for euthanasia of the extracted organisms since the mites are fixed in a 70% ethanol solution

3. Due to the use of the temperature extraction method, there was no impossible to record the symptoms with behavioral and morphology changes of the extracted predatory mites.

The deviations did not affect the study results

GLP: Yes

Acceptability: Yes

Material and Methods

Test item: name: A-200SL-OR3-C; active ingredients content (analysed): acetamiprid: 201.7 g/L, batch number: 3/18; manufacturing date: 11.2018; expiry date: 11.2020

Test organism: The predatory mites, *Hypoaspis* (*Geolaelaps*) *aculeifer* (adult female mites from a synchronized culture) obtained from a standard laboratory culture at the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicological Studies, Laboratory of Soil Toxicology. The mites were introduced 7 – 14 days after becoming adult

Artificial soil

Components:
- 5% sphagnum peat
- 20% kaolin clay
- 75% air-dried quartz sand

maximum water holding capacity: 31.53%
pH: 5.77.
soil dry weight content: 93.9%

Test conditions:

– temperature: 18.5-21ºC
- controlled light – dark cycles (16h : 8h)

Tested concentrations: Nine concentrations of the test item were used in the experiment (0.18, 0.32, 0.56, 1.0, 1.8, 3.3, 5.6, 10.0 and 18.0 mg of the test item/kg of dry weight of the artificial soil).

There were four replicates of each test concentration.

At the same time, an untreated control group (eight replicates) was introduced to the soil without the test item.

The test item in the form of a aqueous solution was mixed with a suitable amounts of the artificial soil.

Study duration: 14 days

Observations: After 14 days: mortality, number of juveniles

Endpoints: NOEC, LOEC, EC_{10}, EC_{20}, EC_{50}, LC_{50}

The aims of the study were to assess the impact of the test item on reproduction of predatory mite, *Hypoaspis aculeifer* and to determine the EC10, EC20, EC50, and NOEC.

Results

Mortality of the predatory mites exposed to the test item at the concentrations ranging from 0.18 to 18.0 mg/kg dry weight of the artificial soil was between 0% and 12.5%. Mortality of the control group was equal to 8.8%.
The concentration of the test item causing a 50% mortality of adults within the exposure period (LC50) is above 18.0 mg/kg dry weight of the artificial soil (above 3.08 mg of acetamiprid/ kg dry weight of the artificial soil).

The number of juveniles at the end of the test is presented in Table 8. whereas the endpoints showing the impact of the test item on reproduction are given in Table 9. The concentration – effect curve showing the influence of the test item on the number of juveniles is presented in Figure 2.
After the application of the test item at the concentrations ranging from 0.18 to 18.0 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 69.5 – 104.3 per replicate. The mean number of juveniles in the control group was equal to 106.5 per replicate.

The obtained results led to the following conclusions:

The concentration of the test item causing a 10% reduction in the number of mites produced within the exposure period (EC10) is equal to 3.31 mg/kg dry weight of the artificial soil (equal to 0.57 mg of acetamiprid/ kg dry weight of the artificial soil).

The concentration of the test item causing a 20% reduction in the number of mites produced within the exposure period (EC20) is equal to 7.31 mg/kg dry weight of the artificial soil (equal to 1.25 mg of acetamiprid/ kg dry weight of the artificial soil).

The concentration of the test item causing a 50% reduction in the number of mites produced within the exposure period (EC50) is above 18.0 mg/kg dry weight of the artificial soil (above 3.08 mg of acetamiprid/ kg dry weight of the artificial soil).

The highest concentration at which the test item is observed to have no statistically significant effects on mite reproduction (NOEC) is equal to 3.3 mg/kg dry weight of the artificial soil (equal to 0.57 mg of acetamiprid/ kg dry weight of the artificial soil).

The impact of the test item on reproduction and on mortality of the predatory mites (Hypoaspis aculeifer) is presented in the table below.

Endpoint	Value [mg/kg dry weight of the artificial soil]	Value [mg of acetamiprid / kg dry weight of the artificial soil]
EC_{10}	**3.31** (1.22 – 5.09)	**0.57** (0.21 – 0.87)
EC_{20}	**7.31** (4.60 – 10.07)	**1.25** (0.79 – 1.73)
EC_{50}	**>18.0**	**>3.08**
NOEC (reproduction)	**3.3**	**0.57**
LC_{10}	**>18.0**	**>3.08**
LC_{20}	**>18.0**	**>3.08**
LC_{50}	**>18.0**	**>3.08**
NOEC (survival)	**≥18.0**	**≥ 3.08**

Validity criteria:

The results are considered valid because the following criteria were satisfied in the control:
• mean adult mortality: 8.8% (criterion: ≤ 20%),
• the mean number of juveniles per vessel at the end of the test: 106.5 (criterion: ≥ 50 juveniles at the end of the test,
• the coefficient of variation for the number of juveniles: 14.2 (criterion: ≤ 30%).

Conclusions

In the 14 - day hypoaspis reproduction study with Leptosar 200 SL, the lowest endpoint (NOEC and EC_{10}) of 0.57 mg ai/kg dws for reproduction was obtained and thus, it is proposed to be used in the risk assessment.

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	The study was conducted to OECD guideline 216 and according to the principles of GLP. The study is considered to be reliable and suitable for the risk assessment.
Reference:	KCP 10.5
Report	Report A-200SL-OR3-C: Soil Microorganisms: Nitrogen Transformation Test according to the OECD Guideline No. 216 (2000)/EU Method C.21. Wołany M. 2019d. STUDY CODE: G/150/18 Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	Yes. According to the OECD Guideline for the Testing of Chemicals No. 216 (2000) / EU Method C.21.
Deviations:	Deviations from the OECD Guideline No. 216 (2000): 1. According the Guideline, the soil extraction should be conducted at 150

rpm for 60 min. However, in this study, the extraction was performed at 90 rpm for 24 hours. The modification resulted from the optimization of the nitrate extraction which showed that the extraction was more effective when the shaking rate was lower and the extraction lasted longer (chapter 3.4.4.4.). These deviations did not affect the results of the study.

GLP: Yes

Acceptability: Yes

Materials and methods

1. Test material: A-200SL-OR3-C

2. Batch number: 3/18
   Concentration of acetamiprid 201.7 g/L

3. Soil: Agricultural soil collected from a place belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna.

4. Test design: test duration: 98days; three portions of soil (3 x 1500 g). i.e. one control group and two treated groups. Every portion was divided into three replicates (3 x 500 g). The soil was enriched with the organic substrate. i.e. lucerne at dose of 5 g/kg dry weight of soil.

The aim of the study was to detect long-term adverse effects of A-200SL-OR3-C on the processes of nitrogen transformation in aerobic surface soils.
Agricultural soil was used. It was manually cleared of large objects and sieved to a particle size of 2 mm.
The concentrations of the test item were:

- PEC: 0.94 mg of the test item / kg dry weight of soil (0.16 mg of acetamiprid / kg dry weight of soil),
- 5 x PEC: 4.7 mg of the test item / kg dry weight of soil (0.8 mg of acetamiprid / kg dry weight of soil).

The treated and the control soils were divided into three replicates.
On days 0, 7, 14, 28, 42, 56, 70, 84 and 98 of incubation, soil samples were collected to determine the quantities of nitrate.
The method involves a measurement of the nitrates ions concentration in a soil extract obtained by using deionised water. The pH/ION 7320 digital meter and the NO 800 nitrate electrode were used.
The nitrate formation rate in each treated group was compared with that in the control, and the percent deviation of the treated from the control was calculated.

Results and discussions

On 28 day of analysis the percent deviation from the control calculated on the basis of the nitrate formation rate of the soil treated with the test item at the concentrations corresponding to the PEC and 5 x PEC exceeded 25% and according to the OECD No. 216 the experiment was continued.
The difference in the nitrate formation rate between the control soil and the one treated with the test item at the concentration corresponding to the PEC: 0.94 mg of the test item / kg dry weight of soil (0.16 mg of acetamiprid / kg dry weight of soil) did not exceed 25% on 42 day of analysis.
The difference in the nitrate formation rate between the control soil and the one treated with the test item at the concentration corresponding to the 5 x PEC: 4.7 mg of the test item / kg dry weight of soil (0.8 mg of acetamiprid / kg dry weight of soil) was exceed 25% on 98 day of analysis.

Table 14. Nitrate formation rate* [mg nitrate/kg dry weight of soil/day] for selected time intervals.

Time interval [d]	Control				PEC				5 x PEC			
	Replicate			Mean ± SD	Replicate			Mean ± SD	Replicate			Mean ± SD
	I	II	III		I	II	III		I	II	III	
0 – 7	1.899	1.320	1.049	**1.423 ± 0.43**	-1.810	-1.096	-0.139	**-1.015* ± 0.84**	19.247	21.990	22.011	**21.082* ± 1.59**
0 – 14	1.546	1.593	1.936	**1.692 ± 0.21**	0.424	1.409	1.702	**1.178 ± 0.67**	14.892	13.595	12.895	**13.794* ± 1.01**
0 – 28	4.146	5.007	5.080	**4.744 ± 0.52**	6.383	5.578	6.499	**6.153* ± 0.50**	11.344	11.411	11.753	**11.503* ± 0.22**
0 – 42	4.461	4.595	4.117	**4.391 ± 0.25**	3.909	4.856	4.476	**4.414 ± 0.48**	9.675	10.619	9.242	**9.846* ± 0.70**
0 – 56	4.777	4.922	4.603	**4.767 ± 0.16**	4.581	4.911	5.203	**4.898 ± 0.31**	8.930	9.037	8.876	**8.948* ± 0.08**

* - Rate of nitrate ions formation per a day = [(mg nitrate / kg of soil dry weight on sampling day 'a') - (mg nitrate / kg of soil dry weight on day 0)]/ 'a' day; 'a' = 7, 14, 28, 42, 56, 70, 84, 98 day

+ - statistically significant difference between the control and the treatment group (STUDENT-t test for homogeneous variances with Bonferroni-Holm adjustment. significance level = 0.05. two sided)

Table 14. cont. Nitrate formation rate* [mg nitrate/kg dry weight of soil/day] for selected time intervals.

Time interval [d]	Control				PEC				5 x PEC			
	Replicate			Mean ± SD	Replicate			Mean ± SD	Replicate			Mean ± SD
	I	II	III		I	II	III		I	II	III	
0 – 70	5.409	5.328	5.818	**5.518 ± 0.26**	4.944	5.171	5.357	**5.157 ± 0.21**	8.159	8.642	8.990	**8.597* ± 0.42**
0 – 84	5.811	6.051	6.098	**5.987 ± 0.15**	5.289	5.839	6.997	**6.041 ± 0.87**	8.386	8.672	9.118	**8.725* ± 0.37**
0 – 98	7.853	8.757	9.418	**8.676 ± 0.79**	7.844	8.693	9.380	**8.639 ± 0.77**	12.014	13.532	12.684	**12.743* ± 0.76**

* - Rate of nitrate ions formation per a day = [(mg nitrate / kg of soil dry weight on sampling day 'a') - (mg nitrate / kg of soil dry weight on day 0)]/ 'a' day; 'a' = 7, 14, 28, 42, 56, 70, 84, 98 day

+ - statistically significant difference between the control and the treatment group (STUDENT-t test for homogeneous variances with Bonferroni-Holm adjustment. significance level = 0.05. two sided)

Table 15. Deviations from the control based on nitrate formation rate for selected time Intervals [%]

Time interval [d]	PEC	5 x PEC
0 – 7	171,35	-1381,69
0 – 14	30,33	-715,46
0 – 28	-29,70	-142,45
0 – 42	-0,52	-124,21
0 – 56	-2,75	-87,70
0 – 70	6,54	-55,80
0 – 84	-0,91	-45,74
0 – 98	0,43	-46,88

"-" – nitrate formation rate in the treatment group was lower than in the control group

Validity criteria:
The coefficients of variation (CV) in the control group were 0.9, 6.3, 4.8, 8.5, 4.7, 2.9, 4.2, 2.3 and 8.4%, after 0, 7, 14, 28, 42, 56, 70, 84 and 98 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than ± 15%.

Conclusion:
As regards to the obtained results, it was concluded that LEPTOSAR 200 SL at the concentrations corresponding to the 0.94 mg of the test item / kg dry weight of soil (0.16 mg of acetamiprid / kg dry weight of soil can be perceived as having no long-term influence on nitrogen transformations in soil.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

Not relevant.

A 2.6.2 KCP 10.6.2 Testing on non-target plants

A 2.6.2.1.1 Study 1

Comments of zRMS:	The study was conducted to OECD guideline 208 and according to the principles of GLP. The study is considered to be reliable and suitable for the risk assessment.

Reference:	KCP 10.6.2/01
Report	Report A-200SL-OR3-C: Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test according to the OECD Guideline No. 208 (2006) . Wołany M, 2019e STUDY CODE: G/152/18 Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	Yes. According to the OECD Guideline for the Testing of Chemicals No. 208 "Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test"
Deviations:	Yes. Deviation from the OECD Guideline No. 208 (2006): 1. According to OECD Guideline No. 208 (2006), the light intensity should be 350 ± 50µE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 78.4 – 141.2 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. The deviation did not affect the results of the study.
GLP:	Yes
Acceptability:	Yes

Materials and methods

1. Test material: A-200SL-OR3-C

2. Batch number: 3/18
   Concentration of acetamiprid 201.7 g/L

3. Test organism: Six plant species were used. These were: sunflower (*Helianthus annuus*), pea (*Pisum sativum*), cabbage (*Brassica oleracea var. capitata)*, carrot *(Daucus carota)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa)*.

4. Test design:

   The study, aimed at evaluating the effect of A-200SL-OR3-C on seedling emergence and seedling growth of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species.

   The test item was sprayed onto the soil surface. Five application rates were used for sunflower, cabbage, pea, carrot, perennial ryegrass and oats. There was also a concurrent control group. Selected number of plants per pot provide the adequate growth conditions and avoid overcrowding during the experiment.

   The number of seeds per pot as well as the total number of seeds per concentration for each of the tested species is presented below:
   - sunflower: 3 seeds/pot – 21 seeds/concentration (7 pots/concentration);
   - pea: 3 seeds/pot – 21 seeds/concentration (7 pots/concentration);
   - cabbage: 3 seeds/pot – 21 seeds/concentration (7 pots/concentration);
   - carrot - 5 seeds/pot – 20 seeds/concentration (4 pots/concentration);
   - perennial ryegrass: 5 seeds/pot – 20 seeds/concentration (4 pots/concentration);
   - oats - 5 seeds/pot – 20 seeds/concentration (4 pots/concentration).

   The experiment was conducted in a special room. Suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for emergence (every day and then every 2 – 3 days) and visual phytotoxicity (after 7 and 14 days). The experiment finished 14 days after the emergence of 50% of the control seedlings. At the end of the experiment, the number of surviving plants was determined. Next, the plants were cut down, measured, dried to a constant weight at 60ºC, and weighed.

Results and discussions:

The results concerning the emergence, the shoot length, and the dry weight were statistically analyzed in order to determine the ER_{25}, ER_{50}, NOER.

The ER_{50} and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as mL of the test item/ ha for all test species are given below.

Endpoint	Sunflower *Helianthus annuus*	Cabbage *Brassica oleracea var. capitata*	Pea *Pisum sativum*	Carrot *Daucus carota*	Perennial ryegrass *Lolium perenne*	Oats *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 300.0	> 300.0	> 300.0	> 300.0	> 300.0	> 300.0
NOER	> 300.0	≥ 300.0	≥ 300.0	11.1	≥ 300.0	≥ 300.0
Shoot length (plants without roots)						
ER_{50}	> 300.0	> 300.0	> 300.0	> 300.0	> 300.0	> 300.0
NOER	≥ 300.0	≥ 300.0	≥ 300.0	≥ 300.0	≥ 300.0	≥ 300.0
Plant dry weight (plants without roots)						
ER_{50}	> 300.0	> 300.0	> 300.0	> 300.0	> 300.0	> 300.0
NOER	≥ 300.0	≥ 300.0	≥ 300.0	≥ 300.0	≥ 300.0	≥ 300.0

The ER50 and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of acetamiprid / ha for all test species are given below.

Endpoint	Sunflower *Helianthus annuus*	Cabbage *Brassica oleracea var. capitata*	Pea *Pisum sativum*	Carrot *Daucus carota*	Perennial ryegrass *Lolium perenne*	Oats *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 60.5	> 60.5	> 60.5	> 60.5	> 60.5	> 60.5
NOER	> 60.5	≥ 60.5	≥ 60.5	2.2	≥ 60.5	≥ 60.5
Shoot length (plants without roots)						
ER_{50}	> 60.5	> 60.5	> 60.5	> 60.5	> 60.5	> 60.5
NOER	≥ 60.5	≥ 60.5	≥ 60.5	≥ 60.5	≥ 60.5	≥ 60.5
Plant dry weight (plants without roots)						
ER_{50}	> 60.5	> 60.5	> 60.5	> 60.5	> 60.5	> 60.5
NOER	≥ 60.5	≥ 60.5	≥ 60.5	≥ 60.5	≥ 60.5	≥ 60.5

The test item, i.e. A-200SL-OR3-C applied at rates ranging from 3.7 to 300 mL of the test item/ha had no impact on the growth and seedling emergence of sunflower, pea, cabbage, perennial ryegrass and oats. The test item had a slight impact on the growth and seedling emergence of carrot.

Plants of all analyzed species emerged at all of analyzed concentrations. The delayed seedling emergence of plant was not observed at cultivation of all analyzed species.

The test item at rates ranging from 3.7 to 300 mL of the test item/ha did not cause mortality of sunflower, pea, cabbage, perennial ryegrass and oats. The test item caused mortality of carrot.

On the basis of NOER, ER25 and ER50 values determined from the shoot length it was proved that the test item did not inhibit the process of all analyzed species.

On the basis of NOER, ER25 and ER50 values determined from the shoot dry weight, it was proved that the test item did not inhibit the process of growth of all analyzed species.

Phytotoxic symptoms were not observed after 7 and 14 days of the exposure in all analyzed species. Results of observations are presented below:

Phytotoxicity effects (Carrot, sunflower, pea, cabbage, perennial ryegrass, oat)				
Application rate (mL of test item/ha)	Day 7		Day 14	
	Mean effect/ application rate (%)	Symptoms	Mean effect/ application rate (%)	Symptoms
0 (control)	0	nc	0	nc
3.70	0	nc	0	nc
11.1	0	nc	0	nc
33.3	0	nc	0	nc
100.0	0	nc	0	nc
300.0	0	nc	0	nc

nc- no changes observed

The following order of the test plant sensitivity was noticed: carrot > sunflower, pea, cabbage, perennial ryegrass, oats.

Validity of the test:

- Seedling emergence in the control was at least 70%
- In none of the control replications of any plants species there were any signs of intoxications visible
- Mean survival of plants in control was 100% for every species (required at least 90%)
- Environmental conditions and soil were identical for all used in the experiment plants species

Conclusion:

Independent on tested species and the analysed parameter the ER_{50} value determined was > 60.5 g ai/ha.

A 2.6.2.1.1 Study 2

Comments of zRMS:	The study was conducted to OECD guideline ~~214~~ 227 and according to the principles of GLP. The study is considered to be reliable and suitable for the risk assessment.

Reference:	KCP 10.6.2/02
Report	Report A-200SL-OR3-C: Terrestrial Plant Test: Vegetative Vigour Test according to the OECD Guideline No. 227 (2006). Wołany M, 2016 f. STUDY CODE: G/151/18. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	Yes. According to the OECD Guideline for the Testing of Chemicals No. 227 "Terrestrial Plant Test: Vegetative Vigour Test".
Deviations:	Yes. According to OECD Guideline No. 227 (2006), the light intensity should be 350 ± 50µE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 70.9 – 191.2 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing.

GLP: Yes

Acceptability: Yes

Materials and methods

1. Test material: A-200SL-OR3-C

2. Batch number: 3/18
   Concentration of acetamiprid 201.7 g/L

3. Test organism: Six plant species were used. These were: sunflower (*Helianthus annuus*), pea (*Pisum sativum*), cabbage (*Brassica oleracea var. capitata)*, carrot *(Daucus carota)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa)*.

4. Test design:

   The study, aimed at evaluating the effect of A-200SL-OR3-C on vegetative vigour of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species.

   Seeds of the test plant species were sown in plastic pots (10 seeds/pot for carrot, oats, perennial ryegrass and 6 seeds/pot for cabbage, pea, sunflower). The plants were grown to the 2- to 4- true leaf stage. Then, some of them were removed.

   As a result, the number of plants per pot as well as the total number of plants per concentration were:
   - sunflower: 3 plants/pot – 21 plants/concentration (7 pots/concentration);
   - cabbage: 3 plants/pot – 21 plants/concentration (7 pots/concentration);
   - pea: 3 plants/pot – 21 plants/concentration (7 pots/concentration);
   - carrot: 5 plants/pot – 20 plants/concentration (4 pots/concentration);
   - perennial ryegrass - 5 plants/pot – 20 plants/concentration (4 pots/concentration)
   - oats - 5 plants/pot – 20 plants/concentration (4 pots/concentration).

   The pot is defined as a replicate. The test item was sprayed onto the plants. For each species, five application rates were used. Untreated control group was conducted simultaneously. The treated and the control groups were divided into four replicates for carrot, oats, perennial ryegrass and 7 replicates for cabbage, pea, sunflower.

   The experiment was conducted in a plant growth room where suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for visual phytotoxicity (7, 14 and 21 days after the test item application). The experiment finished 21 days after the spraying. At the end of the experiment, the number of surviving plants was counted. Next, the plants were cut down, and the lengths of their shoots were determined. Finally, they were dried at 60ºC to a constant weight and weighed.

Results and discussions:

The results concerning the shoot length, the dry weight, and the number of plants at the end of the experiment were statistically analyzed to determine the ER25, ER50, and NOER.

The ER50 and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as mL of the test item/ ha for all test species are given below.

	Sunflower *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Perennial ryegrass** *Lolium perenne*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 300.0	> 300.0	> 300.0	> 300.0	> 300.0	> 300.0
NOER	> 300.0	> 300.0	> 300.0	> 300.0	> 300.0	> 300.0
Shoot length (plants without roots)						
ER_{50}	> 300.0	> 300.0	> 300.0	> 300.0	> 300.0	> 300.0
NOER	≥ 300.0	≥ 300.0	≥ 300.0	≥ 300.0	≥ 300.0	≥ 300.0
Plant dry weight (plants without roots)						
ER_{50}	> 300.0	> 300.0	> 300.0	> 300.0	> 300.0	> 300.0
NOER	≥ 300.0	≥ 300.0	≥ 300.0	≥ 300.0	≥ 300.0	≥ 300.0

The ER50 and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of acetamiprid /ha for all test species are given below.

	Sunflower *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Perennial ryegrass** *Lolium perenne*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 60.5	> 60.5	> 60.5	> 60.5	> 60.5	> 60.5
NOER	> 60.5	> 60.5	> 60.5	> 60.5	> 60.5	> 60.5
Shoot length (plants without roots)						
ER_{50}	> 60.5	> 60.5	> 60.5	> 60.5	> 60.5	> 60.5
NOER	≥ 60.5	≥ 60.5	≥ 60.5	≥ 60.5	≥ 60.5	≥ 60.5
Plant dry weight (plants without roots)						
ER_{50}	> 60.5	> 60.5	> 60.5	> 60.5	> 60.5	> 60.5
NOER	≥ 60.5	≥ 60.5	≥ 60.5	≥ 60.5	≥ 60.5	≥ 60.5

The test item, i.e. A-200SL-OR3-C applied at rates ranging from 3.7 to 300 mL of the test item/ha had no impact on vegetative vigour of all analyzed species.

The test item did not cause mortality of all analyzed species.

On the basis of NOER, ER25 and ER50 values determined from the shoot length it was proved that the test item did not inhibit the process of growth of all analyzed species.

On the basis of NOER, ER25 and ER50 values determined from the dry shoot weight it was proved that the test item did not inhibit the process of growth of all analyzed species.

No phytotoxic symptoms were observed in all analyzed species. Results of observations are presented below:

Phytotoxicity effects **(Carrot, sunflower, pea, cabbage, perennial ryegrass, oat)**						
Application rate (mL of test item/ha)	Day 7		Day 14		Day 21	
	Mean effect/ application rate (%)	Symptoms	Mean effect/ application rate (%)	Symptoms	Mean effect/ application rate (%)	Symptoms
0 (control)	0	nc	0	nc	0	nc
3.70	0	nc	0	nc	0	nc

11.1	0	nc	0	nc	0	nc
33.3	0	nc	0	nc	0	nc
100.0	0	nc	0	nc	0	nc
300.0	0	nc	0	nc	0	nc

nc- no changes observed

Validity of the test:

- Seedling emergence in the control was at least 70%
- In none of the control replications of any plants species there were any signs of intoxications visible
- Mean survival of plants in control was 100% for every species (required at least 90%)
- Environmental conditions and soil were identical for all used in the experiment plants species

Conclusion:
Independent on tested species and the analysed parameter the ER_{50} value determined was > 60.5 g ai/ha.

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

Not relevant.

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

Not relevant.

A 2.8 KCP 10.8 Monitoring data

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